Chapter 4
Evaluating the Tier I Baseline Ecological Risk Assessment

4.1 Introduction

This chapter introduces the conceptual and technical objectives for evaluating a Tier I baseline ERA. The Tier I ERA is characterized by relatively simple, quantitative wherever possible, desk-top methods that rely heavily on literature information, previously collected data, and a chemical concentration-based approach. The Tier I ERA emphasizes adverse effects to the individual based on literature-cited toxicity values with extrapolations to potential impacts at the population, community, or ecosystem level. The Tier I ERA provides quantitative chemical information for the exposure point media (e.g., soils, sediments, surface water) and possibly qualitative biological data to fill gaps in the available data set. Field or laboratory bioassays are typically not part of a Tier I effort. Any biological samples collected are co-located to the extent possible with abiotic media samples. The Tier I ERA includes the establishment of appropriate ecological endpoints (ecological components affected by chemical exposure) for the chemicals of potential concern. Tier I activities are essentially a more advanced form of screening with emphasis on the following:

- Compiling and evaluating available data and information.
- Identifying critical information gaps.
- Determining the need for design and implementation of remedial activities.
- Ascertaining the need for detailed field studies prior to design and implementation of remedial activities.

Development of a site-specific ECSM, selection of potential COECs, and a description of exposure pathways are major activities in this tier. Qualitative and quantitative data from a site reconnaissance or field survey of flora and fauna are summarized in an ecological site description. This field visit coupled with site-specific information provides for documentation of obvious adverse effects, identification of potentially important receptors, and development of simplified food web models to evaluate the potential for COECs to bioaccumulate in receptors of concern.

Abiotic concentration data are used to establish exposure concentrations for the receptors of concern. Preliminary effects estimates are based on regulatory and literature values. Quotient calculations in conjunction with available toxicity information, exposure concentrations, and reasonable, conservative assumptions are used to provide initial risk estimates.

The main output from Tier I is a detailed, site-specific technical report, If the information provided by the Tier I ERA is adequate to support decisions in the FS/RD-RA, no further ERA sampling or analyses are needed. If, however, there are insufficient data (i.e., too much uncertainty in the ERA) to reach FS/RD-RA decisions, additional biotic and abiotic data needs will be identified, the data collected, and a more definitive assessment performed within Tier II, III, or IV.

In the following sections of this chapter, the individual steps required to prepare a Tier I ERA are introduced and discussed. Exhibits and a case study (CS) are also provided to illustrate the performance of these various steps (see CS 1). Exhibits are located after Chapter 9. The steps to perform a Tier I ERA are grouped as follows, in general accordance with EPA's *Framework:*

- PROBLEM FORMULATION:
  Ecological site description
  Chemical data collection and review
  Selection of preliminary COECs
  Selection of key receptors
  Ecological endpoint (assessment and measurement) identification
  ECSM
- ANALYSIS PHASE -

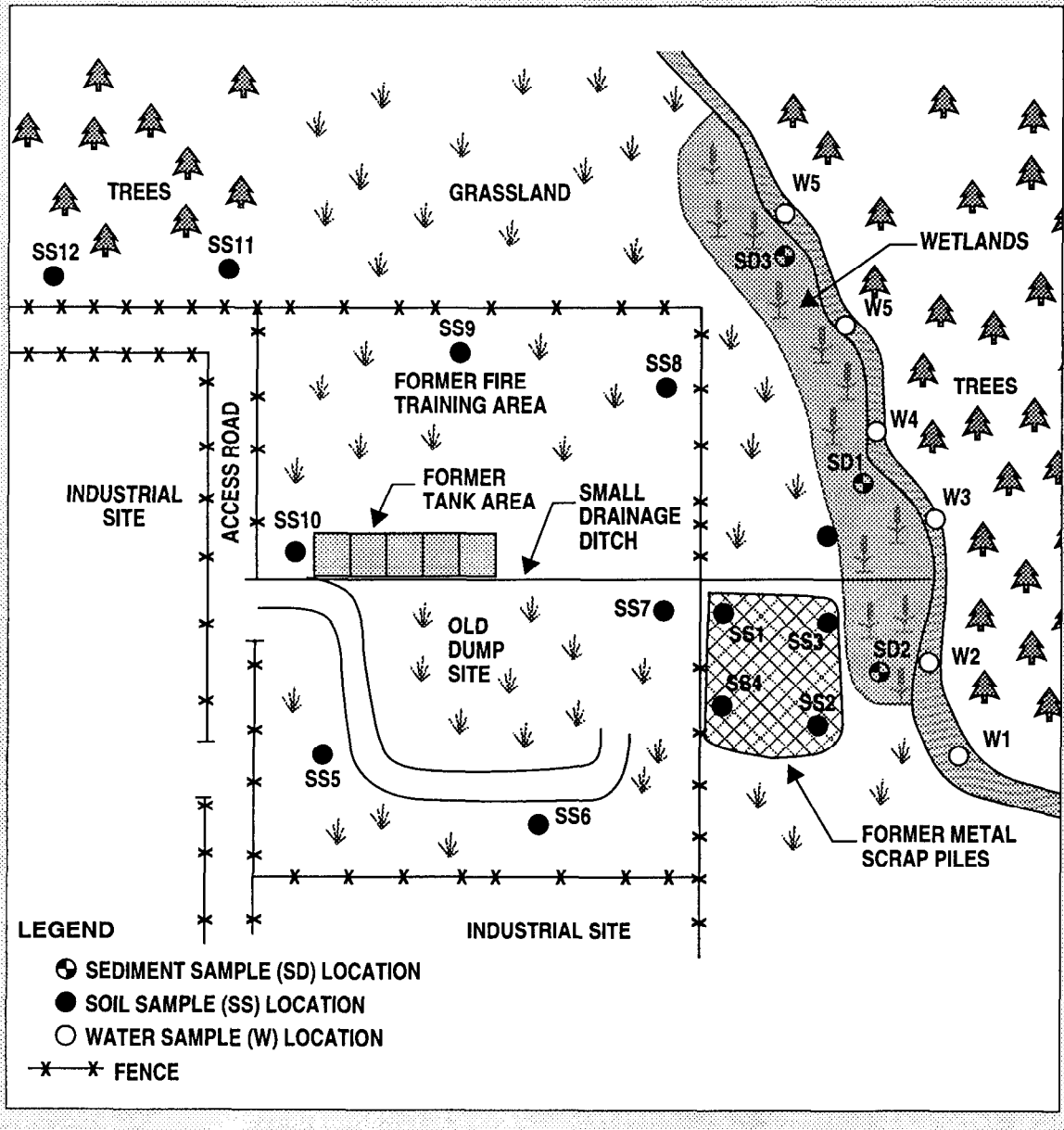
  EXPOSURE CHARACTERIZATION:
  Exposure analysis
  Exposure profiles

  ECOLOGICAL EFFECTS CHARACTERIZATION:
  Selection of literature benchmark values
  Development of reference toxicity values
- RISK CHARACTERIZATION:
  Risk estimation
  Risk summary
  Uncertainty characterization

CASE STUDY 1

SITE SETTING

For the purposes of demonstrating performance of a baseline ERA, a case study is provided throughout this section. Major steps in the ERA process are demonstrated in the following pages.



Our case study site is a former fire training area of a formerly used defense (FUD) site. The site contained a gasoline storage area near an old dump site. It is believed that only gasoline was stored in the tanks but the old records have been lost, and storage of other petroleum products or solvents may have occurred. Records on materials placed in the old dump site were also not available. There is some anecdotal information suggesting that chlorinated solvents were also dumped or burned. The gasoline storage tanks have been removed. A portion of the old dump contained some metal scrap piles that have been removed. The site is being investigated for possible chemical releases to the surrounding environment. As part of the site investigation, a baseline ERA is being performed to determine whether the chemical releases, if any, pose adverse ecological risks.

The setting of the site is shown above in this case study. The area east and north of the site is a mixture of undeveloped grassland and woodland. A small drainage ditch between the old dump site and fire training area leads to a small stream and wetland area of about 5 acres.

A preliminary investigation/site assessment (PA/SI) was performed by the state, providing the following information:

- When tanks were removed, they were found to contain holes;
- Soils in the tank excavation pits were tainted and had a petroleum odor;
- Surface soils were sampled at two locations (SS1 and SS2) during the PA/SI and analyzed for metals only. Soils were found to contain arsenic, barium, cadmium, nickel, and lead. No information on background soil quality is available.

As the risk assessor for the site, you have been asked to provide input into the development of the sampling and analysis plan (SAP), the quality assurance project plan (QAPP), and subsequent investigations.

The sequence of steps presented above is similar to the format used in most ERA documents. The actual sequence of events followed in the conduct of an ERA, however, can be quite variable and is frequently dependent on data availability, time availability, and the individual nature of the site and project. While the steps listed above are generally the same in each of Tiers I through IV, each may receive different emphasis depending on the tier and hence level of complexity of the baseline ERA.

4.2 Problem Formulation

Problem formulation is used to establish the goal, scope, and focus of the Tier I ERA. This systematic planning phase identifies the major factors to be considered in evaluating ecological risks associated with a given site and its linkage to the regulatory and policy context of the assessment. Problem formulation provides an early identification of key factors to be considered in the Tier I ERA. The problem formulation stage thereby encompasses the creation of PD statements to represent the specific planning objectives of the Tier I effort.

Once triggered, the problem formulation process begins a preliminary (largely conceptual) characterization of exposure and effects. This involves evaluating the potential COECs present, the ecosystems and receptors potentially at risk, the ecotoxicology of the contaminants known or suspected to be present, and observed or anticipated ecological effects. Then, ecological endpoints to be addressed and/or measured are identified (see Section 4.2.5). The process culminates in a preliminary ECSM that identifies potential exposure pathways, environmental values (receptors) to be protected, impacts or adverse effects to be evaluated, data needed, and analyses to be used (see Section 4.2.6).

4.2.1 Ecological Site Description

An initial site description is needed to orient the technical specialists. This information should be assembled from existing sources of information, without conducting formal field studies. Initially, base or facility natural resource personnel should be contacted as they often have relevant data or useful ecological information. Many state and Federal agencies can provide information on sensitive areas or regional data on ecology, especially threatened and endangered species, checklists of biota, endemic species, and other pertinent ecological information. These agencies include USFWS, local and state planning agencies, 404 staffs in EPA regions, state fish and wildlife agencies, and perhaps the new USDOI National Biological Survey in the near future. Surveys conducted by the Nature Conservancy or state Natural Heritage Programs may also be available.

Much information may be available from published sources such as soil survey and topographic maps, National Wetlands Inventory Maps (NWI), and information from natural history or heritage program databases or from previous assessments of the site. In addition, experts at local or regional universities often can provide information on wetland species, bird checklists, mollusks, plants, or other specialties. Local, regional, or university museums or state biological surveys may be other sources of information.

Presence of wetlands, threatened or endangered species, endemic species, or lands or waters containing species considered as or classified as having a “high” value will significantly impact problem formulation and planning for conduct of the ERA. Where waters of the state are involved, the National Pollutant Discharge Elimination System (NPDES) permitting agency may be a good source of information especially if they have conducted use attainability studies for the purpose of classifying the uses or have permitted discharges to the waters.

4.2.1.1 Reconnaissance (Biota Checklist)

Much of the information sought during a site reconnaissance is commonly available information. However, it is essential that a site reconnaissance and ecological site characterization be conducted in this stage by an ecologist.

Prior to arrival at the site, the ecologist should be provided with information on the site, including topographic maps; township, county or other appropriate maps: location of potential ecological units such as streams, lakes, forest, grasslands, floodplain and wetlands on or near the site: soil types: and local land uses. Much of this information may already have been obtained and documented as part of the PA/SI effort. A checklist with information similar to that on EPA’s (1993a) ***Checklist for Ecological Assessment/Sampling*** should be completed, if it was not completed as part of the PA/SI.

The location of known or potential contaminant sources affecting the site and the probable gradient or pathway by which contaminants may be released from the site to the surrounding environment should be determined to the extent possible based on observations and available information from earlier studies (i.e., PA/SI or RFA). If waters of the state or the U.S. are potentially involved, their designated uses should be determined, so that the

ecologist can make a preliminary qualitative determination as to whether such uses are apparently being achieved.

Ecologists can use the reconnaissance to evaluate the site for more subtle clues of potential effects from contaminant release. For example, the noticeable absence of flora or fauna where otherwise expected may be a clue to potential contaminant effects or other stressors. Absence of the flora understory from a forest may be an indication of soil contamination and the inability of shorter lived forbs and shrubs to reestablish themselves. On the other hand, unusually high numbers of a particular species or unusually thick accumulation of litter may indicate the absence of predators or disruption of nutrient cycling processes. Such ecological observations are important clues to DQO development, the data interpretation effort, and the weight-of-evidence presented in the subsequent risk characterization.

4.2.1.2 Documentation of Potential Receptors of Special Concern and Critical Habitat

The site reconnaissance, in combination with published resources, and information obtained from state and Federal fisheries and wildlife agency experts, should be used to determine if the site or nearby site areas have designated wetlands or critical or sensitive habitats for threatened or endangered species. If such species or entities are present, they must receive special protection during all aspects of the project planning and implementation following consultation with appropriate regulatory authorities.

During the reconnaissance, a checklist of biological species should be developed. From this list, receptors of special concern will be identified. Depending on the sources and potential transport pathways, these receptors could include major elements of the given food chain from plants to higher trophic levels such as insects, reptiles, birds, and mammals. Aquatic ecosystems, for example, can include aquatic plants, bottom fauna (e.g., insects, mollusks), amphibians, turtles, piscivorous snakes, fish, wading birds or ducks, and predatory raptors.

Receptors am the components of ecosystems that are or may be adversely affected by a chemical or stressor. In the Tier I investigation, species, species groups, functional groups (e.g., producer, consumer, decomposer), food guilds (i.e., organisms with similar feeding habits), and critical habitats are the focus of receptor selection. Receptors can be any part of an ecological system, including species, populations, communities, and the ecosystem itself. Toxicity of chemicals to individual receptors can have consequences at the population, community, and ecosystem level. Population level effects may determine the nature of changes in community structure and function, such as reduction in species diversity, simplification of food webs, and shifts in competitive advantages among species sharing a limited resource. Ecosystem functions may also be affected by chemicals, which can cause changes in productivity, or disruption of key processes (alteration of litter degradation rate). Because it is difficult to assess potential impacts to all receptors, a smaller group of receptors of concern (key receptors) is used to assess potential harm to all components of the system. In the Tier I ERA, specific organisms or groups (e.g., small herbivores) are usually selected as key receptors.

4.2.1.3 Significant Ecological Threats

The questions the risk assessor must keep in mind are "Do any ecological threats exist?" and "Are these ecological threats related to chemical contamination?" Using the information discussed above, the risk assessor can begin to identify the habitats potentially affected by contaminants at the site. Decisions can be partly based on absence of biota where expected, especially if plant or animal life is absent along likely contaminant exposure pathways. For example, if areas within the project exposure pathways(s) are devoid of plant life or are obviously stressed, a significant ecological threat probably exists. If there is a groundwater or surface water discharge zone to a stream that is affected by site chemicals and depleted of biota, that would be an obvious significant ecological threat. If effects are less obvious, then it may be necessary to use a more sophisticated approach to determine any impacts, such as a comparison of site biota diversity and relative numbers to an unaffected reference site within or adjacent to the watershed.

4.2.2 Chemical Data Collection and Review

Planning, collection, and review of chemical data constitute the initial and often the most substantial level of effort in a Tier I ERA. Because of the importance for obtaining useable data to the end goal of an acceptable ERA, the following sections describe the data collection and review process in detail (including elements as described in the HTRW technical project planning guidance document).

4.2.2.1 Planning and Providing Input to Data Collection

The ecological risk assessor can effectively contribute to the data collection process when he/she is involved early

on and has some information regarding the ecological setting and the contamination history of the site. To effectively contribute to the overall data collection and analysis process, the risk assessor should be knowledgeable and experienced with the overall DQO process.

To plan and provide input to the data collection effort, the risk assessor should follow the three DQO steps recommended by EPA (1989c) ***in*** the ***Field and Laboratory Reference Document.*** Step I of the process includes preparing definitions of the problem and concise (as possible) statements of the questions to be answered. Examples of Step I DQOs include the following:

- Identify potential and appropriate site-specific receptors, potential COECs, and potential exposure pathways to assess the potential for adverse effects to occur to biological resources as a result of contamination.

- Evaluate the potential for impacts to occur to biological resources outside the current site boundaries.

- Evaluate the need for remediation to protect the environment.

Steps II and III of the DQO process include identification of data needed to answer questions identified in Step I and design of the data collection program (i.e., the data quality design process). Products of Step II include proposed statements of the type and quality of environmental data required to support the DQOs, along with other technical constraints on the data collection program. The objective of Step III is to develop data collection plans that will meet the criteria and constraints established in Steps I and II. Step III results in the specification of methods by which data of acceptable quality and quantity will be obtained (ER 1110-l-263). The DQO development process is flexible and may continue throughout the baseline ERA.

Data needs for the ERA are likely to overlap with those for the human health risk assessment or other data users in specific physical areas of a site. The potential for data need overlaps should be identified early on. Nearby surface waterbodies that are potentially linked to the source through chemical fate and transport are typically sampled for human health purposes. Sediment samples may also be desired by the human health risk assessor, but human exposure points may be different from ecological ones, so proposed sample locations should be reviewed. The ecological risk assessor may need water and sediment samples from specific locations such as where waterfowl are feeding or where effects on benthic communities are likely to occur. Similar data needs should be determined early on by the human health and ecological risk assessors for the elimination of unnecessary work or redundancies in sampling.

Development of a preliminary ECSM is useful in planning for identifying data that will be needed (i.e., sampling and analysis plan) in the ERA (see Section 4.2.6) (see CS 2 and CS 3). An ECSM identifies the likely source(s) of chemicals, the chemical release mechanisms, fate and transport potential, and the resultant secondary and tertiary media that may be impacted. The ECSM also (1) identifies plausible food webs at the site, (2) identifies all potential pathways from chemicals at the source to receptors of concern, and (3) evaluates the completeness of potential exposure pathways, based on known nature and extent of contamination and ecology of species and communities potentially occurring at the site. In essence, the ECSM describes the exposure pathways or routes a chemical takes from point of release from the chemical source to receptors of potential concern. The ECSM is thus a summary of some portions of the exposure characterization. By identifying the potential abiotic media that may need to be assessed in the ERA, and the potential exposure routes by which ecological receptors may be exposed, the ECSM can identify the type of data needed in the ERA. Section 4.2.6 discusses the ECSM in more detail.

Historical data collected for purposes other than the ERA may be available from previous investigations, facility records, permit applications, or other sources. Often, use of historical data sets is limited by the lack of information on sample locations, analytical methods, detection limits, laboratory and quality assurance/quality control (QA/QC) procedures, or scope of analyses. Data from historical sources, therefore, may not be appropriate to use in the quantitative ERA; however, they often can be used in a supportive, qualitative role. When evaluating historical or purposely collected data, a number of factors need to be evaluated. Some factors that should be considered are presented in Exhibit 2.

On the other hand, unique data needs may also be identified early on in the PA/SI or Tier I ERAs that would require purposive (biased) sampling in order to collect abiotic samples from specific areas of contaminant or ecological concern. Onsite animal activity should be initially observed to best evaluate obvious activity patterns relative to the contaminant source areas. For example, if

CASE STUDY 2

DEVELOPMENT OF A PRELIMINARY ECOLOGICAL CONCEPTUAL SITE MODEL

The first step in developing a credible sampling design to support the risk assessment is to formulate an ecological conceptual site model (ECSM). Development of an ECSM is discussed in Section 4.2.6, which should be consulted in conjunction with this case study step. First, some hypothesis of chemicals potentially present on site is needed.

The existence of gasoline or petroleum tanks and possible disposal of solvents suggest the following chemicals may be present:

- Benzene, toluene, ethylbenzene, xylenes (BTEX)
- Polycyclic aromatic hydrocarbons (PAHs)
- Trichloroethylene and other chlorinated solvents

The surface soil analyses detected the following metals:

- Arsenic
- Barium
- Cadmium
- Nickel
- Lead

In order to evaluate how and where chemicals may migrate from the site, and in what media the chemicals may be located, the following information is needed for each chemical:

- Water solubility (S);
- Tendency to bind to soil (K_{oc});
- Tendency to accumulate into animal tissue (BCF); and
- Volatility (vapor pressure or Henry's Law Constant).

Obtain these chemical and physical parameters, and anticipate how the potential chemicals may be released and migrate from the site. Then, develop a preliminary ECSM, starting with the primary source areas and progressing to secondary and tertiary sources, and through specific release and migration mechanisms.

CASE STUDY 3

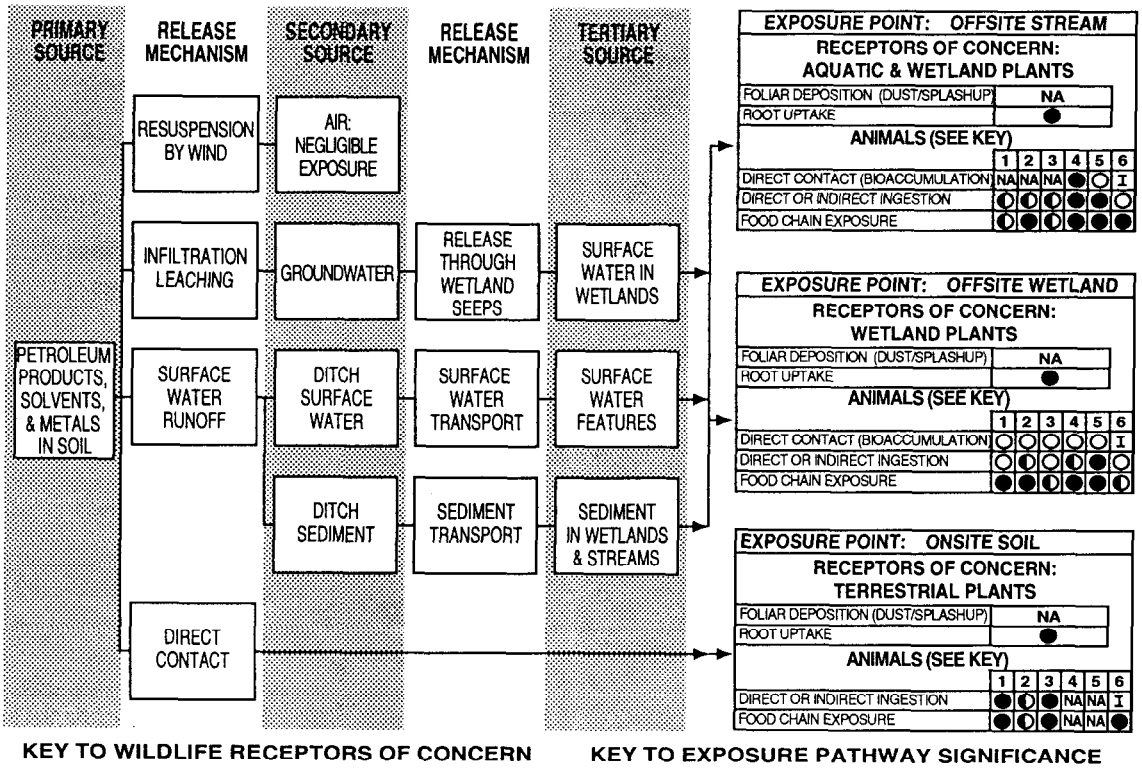
DIAGRAMMING THE ECSM

The ECSM is developed and diagrammed by examining the sources of chemicals and possible release mechanisms, based on an understanding of the fate and transport characteristics of chemicals potentially present on site. A diagram of the ECSM is shown in Example 1 ECSM.

Primary Sources

Preliminary information suggests four possible sources of chemical release to the environment: (1) the former tanks, (2) the old site, (3) the old burn pit, and (4) scrap metal piles. Release at each of these sources may have contaminated soils at the site. Because the original sources have been removed and operations have ceased, soil is considered the primary source of potential contaminant release to the environment.

Example 1 ECSM



KEY TO WILDLIFE RECEPTORS OF CONCERN

① MAMMALIAN HERBIVORES
② MAMMALIAN OMNIVORES AND CARNIVORES
③ AVIAN OMNIVORES
④ AQUATIC INVERTEBRATES AND INFAUNA (ANIMALS)
⑤ WADING BIRDS
⑥ PREDATORY RAPTORS

KEY TO EXPOSURE PATHWAY SIGNIFICANCE

NA NOT APPLICABLE
I INCOMPLETE
○ EXPOSURE POTENTIAL RELATIVELY LOW
◐ EXPOSURE POTENTIAL INTERMEDIATE
● EXPOSURE POTENTIAL RELATIVELY HIGH

Primary Release Mechanisms

Preliminary information suggests the following release mechanisms:

- Resuspension by wind;
- Infiltration and leaching to groundwater from the burn pit, tank area, and scrap piles;
- Surface water runoff from the tank area and scrap piles; and
- Direct contact with site soils.

Secondary Sources

Primary releases from contaminated soils may have resulted in secondary contamination of the following environmental media:

- Groundwater beneath the site;
- Surface water in the ditch;
- Sediments in the ditch or adjacent stream and wetlands; and
- Air.

Due to ecological and climatic conditions, exposure to airborne contaminants is usually considered negligible with respect to the other primary exposure pathways. Lichens, however, are one example of a receptor group that is exceptionally sensitive to airborne contamination.

Secondary Release Mechanisms

Fate and transport information suggests the following secondary release mechanisms:

- BTEX and solvents in groundwater may be released to surface water at the wetland seeps;
- Metals and organic contaminants in ditch surface water may be transported in surface water to the wetland and stream;
- Metals, PAHs, and other organic contaminants in sediment may be transported to the wetland and stream; and,
- BTEX and solvents in soil or groundwater may volatilize to air (not shown in ECSM).

Tertiary Sources

From the above secondary release mechanisms, the potential tertiary sources are:

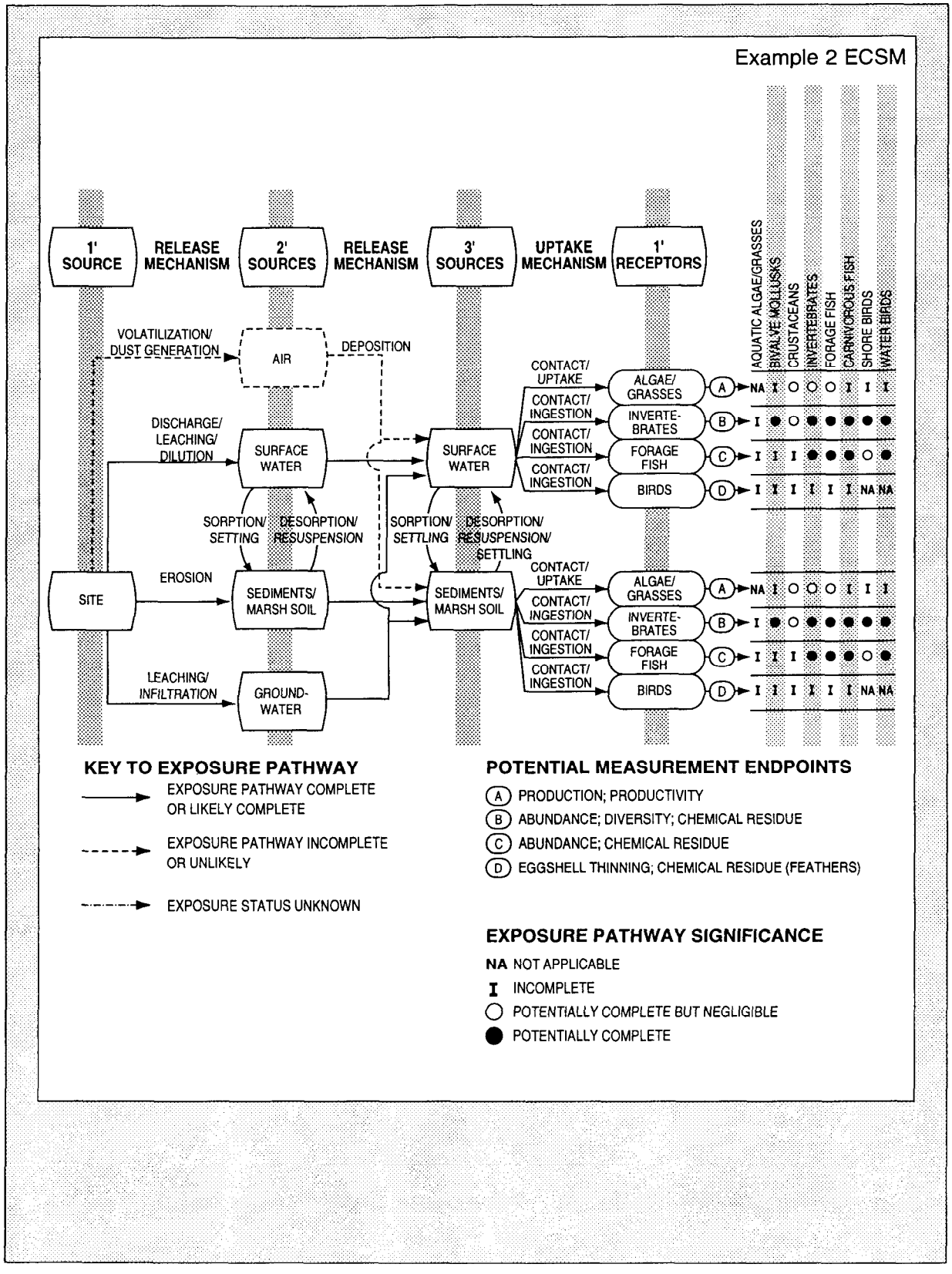
- Surface water in wetlands and the stream; and
- Sediments in wetlands and the stream.

Primary Potential Exposure Pathways

The primary potential exposure pathways for ecological receptors include the following:

- Ingestion of surface soils (on-site);
- Root uptake from soil by terrestrial plants;
- Root uptake from water or sediment by aquatic and wetland plants;
- Direct contact/bioaccumulation from surface water by aquatic animals;
- Ingestion of surface water;
- Ingestion of sediments; and
- Food chain exposure.

This completes the preliminary ECSM. An additional ECSM diagram is shown in Example 2 ECSM.


Example 2 ECSM
1' SOURCE
RELEASE MECHANISM
2' SOURCES
RELEASE MECHANISM
3' SOURCES
UPTAKE MECHANISM
1' RECEPTORS
AQUATIC ALGAE/GRASSES
BIVALVE MOLLUSKS
CRUSTACEANS
INVERTEBRATES
FORAGE FISH
CARNIVOROUS FISH
SHORE BIRDS
WATER BIRDS
VOLATILIZATION/ DUST GENERATION
AIR
DEPOSITION
DISCHARGE/ LEACHING/ DILUTION
SURFACE WATER
SURFACE WATER
SORPTION/ SETTING
DESORPTION/ RESUSPENSION
SORPTION/ SETTLING
DESORPTION/ RESUSPENSION/ SETTLING
EROSION
SITE
SEDIMENTS/ MARSH SOIL
SEDIMENTS/ MARSH SOIL
LEACHING/ INFILTRATION
GROUND-WATER
CONTACT/ UPTAKE
CONTACT/ INGESTION
ALGAE/ GRASSES
INVERTE-BRATES
FORAGE FISH
BIRDS
A
B
C
D
NA I ○ ○ ○ I I I
I ● ○ ● ● ● ● ●
I I I ● ● ● ○ ●
I I I I I I NA NA
KEY TO EXPOSURE PATHWAY
EXPOSURE PATHWAY COMPLETE OR LIKELY COMPLETE
EXPOSURE PATHWAY INCOMPLETE OR UNLIKELY
EXPOSURE STATUS UNKNOWN
POTENTIAL MEASUREMENT ENDPOINTS
(A) PRODUCTION; PRODUCTIVITY
(B) ABUNDANCE; DIVERSITY; CHEMICAL RESIDUE
(C) ABUNDANCE; CHEMICAL RESIDUE
(D) EGGSHELL THINNING; CHEMICAL RESIDUE (FEATHERS)
EXPOSURE PATHWAY SIGNIFICANCE
NA NOT APPLICABLE
I INCOMPLETE
○ POTENTIALLY COMPLETE BUT NEGLIGIBLE
● POTENTIALLY COMPLETE

receptors of special concern are observed on site, it may be advisable to collect chemical sample(s) from their specific habitat.

The need to detect contaminants at extremely low concentrations may also be a unique data need for the ERA. For example, some polycyclic aromatic hydrocarbons (PAHs) (naphthalene, benzo-a-pyrene, and phenanthrene) have reported effects levels in sediments below the certified reporting limits (CRLs) for these chemicals. Also, matrix effects interference in soil and sediment sampling often results in detection limits well above ecological effects levels. While it may be desirable, it is not always possible to have the CRLs or detection limits lower than the effects levels. Such considerations, however, are important to the data collection planning process, the data interpretation, and resultant risk characterization.

The risk assessor's data needs definition for a site is the culmination of the assessor's effort to conceptualize and develop a strategy for conducting the baseline ERAs, based on available chemical and ecological information. Often, the ecological risk assessor is invited to merely comment or advise on a sampling program that has already been devised for other users. Other times, the ecological risk assessor may be largely responsible for design of the entire sampling program. The level of effort for this task may range from minimal to large and complex. Further details on technical project planning and designing a data collection program for an ERA are presented in the following section and in EM 200-1-2 HTRW ***Technical Project Planning*** document USACE (1995b).

4.2.2.2 Evaluation of Available PA/SI Chemical Data

Quality chemical data from the PA/SI data collection effort should be available for use during problem formulation and conduct of the Tier I ERA. Knowledge about historical use of the site should provide information about potentially present contaminants. Available PA/SI chemical data and physicochemical data (organic carbon content, pH, etc.) for abiotic media are used in the screening process to compare measured values with selected toxicity benchmarks for those media. This information in concert with observations made during the reconnaissance and professional judgment are used to characterize risk and evaluate the potential need for a Tier II, III, or IV ERA.

The need to proceed to Tier II biological sampling could be indicated by exceedance of the toxicity benchmarks or other regulatory criteria or by the presence of organic chemicals that biomagnify. Organic chemicals with bioconcentration factors (BCFs) greater than 100 (on a 3% mean lipid content) or log K_{ow} (logarithm of the n-octanol water partition coefficient, log P) values greater than 3.5 are of greatest concern (EPA 1991e) due to their potential to biomagnify in ecological systems. Organic chemicals with BCFs greater than 300 are considered to be of significant concern in aquatic ecosystems, while for terrestrial organisms, BCFs as little as 0.03 can be significant if the residue is toxic (EPA 1989a). Chemicals with water solubilities less than 50 mg/L and potential for significant partitioning into environmental media other than air and water would also be of concern. The presence of chemicals that can biomagnify generally results in a greater level of effort for characterizing risk in Tier I or in the need to proceed to Tier II biological sampling.

Care should be taken where data collected during the PA/SI are largely intended for use in the human health risk assessment, as detection limit needs can be different for the two assessments. For example the drinking water criterion for copper is 1.3 mg/L, while the chronic aquatic life criterion for copper at 100 mg/L $CaC0_3$ hardness is much lower (12 pg/L). Conversely, some of the listed carcinogenic organic compounds are relatively nontoxic to aquatic life, but have extremely low human consumption criteria limits. The PA/SI environmental media data should be evaluated to determine whether chemical concentrations exceed ARARs or guidance criteria. Where data gaps are identified (e.g., chemical data are not available for the location or media of ecological interest), then planning for additional data collection should be undertaken (see CS 4).

4.2.2.3 Review of Analytical Data

The quality of an ERA depends directly on the quality of the chemical data applied. Regardless of how well other components of the Tier I ERA are performed, if data quality is poor or data do not accurately reflect site contamination or the types of exposures assessed, the Tier I ERA will not provide an adequate description of potential adverse ecological effects posed by the site. Therefore, it is imperative that data types used in the assessment be carefully evaluated and properly used.

Planning for appropriate data acquisition is an important step in obtaining the necessary, high quality data. During this planning stage, appropriate location, number and types of samples, detection limits, and analytical methods can be specified as part of the DQQ process. These and

CASE STUDY 4

DEVELOPMENT OF A SAMPLING AND ANALYSIS PLAN

Evaluation of the existing data for our site has concluded the following:

- Releases of metals to surface soils, surface water, and sediments have potentially occurred;
- Petrolcum/solvent releases to surface and subsurface soils have occurred; and
- Volatile organic compound releases to groundwater and subsequent release to wetland and creek sediments and surface water may have occurred.

The ECSM suggests the following:

- Volatile and semivolatile organic compounds may be present in the soil; and
- Semivolatile organic compounds and metals may be present in the soils, sediments, and surface water over a greater area than expected.

The following data gaps are identified:

- There are no data on volatile or semivolatile organic compounds in surface or subsurface soils and metals data in soils are limited;
- There are no surface water or sediment data for organic compounds or metals; and
- Information on groundwater flow direction is not available.

Data quality objectives for additional sampling include:

- Collection of additional soil samples for metals, volatile and semivolatile organic compounds;
- Collection of sediment and surface water samples for metals, volatile and semivolatile organic compounds;
- Collection of groundwater samples for metals, volatile and semivolatile organic compounds and for water table levels; and
- Collection of background surface soil, groundwater, surface water and sediment samples.

other minimum requirements for ERA data should be specified prior to data collection by having the risk assessor involved in early stages of site planning. Once available, a thorough review of the data is needed to ensure that DQOs and minimum requirements have been met. This further ensures that the most appropriate information is used in the ERA.

Numerous factors may potentially have to be considered when identifying minimum data collection requirements for an ERA, or when reviewing existing data to determine useability in an ERA. Relevant guidance on data useability in ERAS is published in the following EPA documents (also see Appendix B):

- *Guidance for Data Useability in Risk Assessments* (Parts A and B) (EPA 1992d,e)
- *Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analysis* (EPA 1994c)
- *Laboratory Data Validation Functional Guidelines for Evaluating Organics Analysis* (EPA 1994d)

An evaluation of data quality should examine the following five broad categories:

- Data Collection Objectives (discussed above).
- Documentation.
- Analytical Methods/Quantitation Limits (see Exhibit 3).
- Data Quality Indicators (see Exhibit 4).
- Data Review/Validation (see Exhibit 5).

Each of these categories contain other factors that should be considered, as well. In some cases, portions of the evaluation are performed by practitioners other than the risk assessor (for example, data validation is most often performed by a qualified chemist): in other cases, the risk assessor must take the lead in acquiring and reviewing the information. In either case, the risk assessor must be aware of the important factors within each category to enable him or her to judge whether the data are appropriate for inclusion in an ERA. Further discussion of the data quality evaluation process is presented in Appendix D (HTRW *Technical Project Planning Process).*

4.2.2.4 Data Presentation and Summary

Data that have been identified as acceptable for use in the Tier I ERA should be summarized in a manner that presents the pertinent information to be applied in the ERA (see CS 5). Any deviations from the DQOs or minimum requirements should be identified, and the potential effect upon the ERA described in the assessment. Any data that have been rejected as a result of the data evaluation should be identified, along with a reason for their rejection.

At this point in the Tier I ERA, all appropriate site data identified as acceptable by the data evaluation process should be combined for each medium for the purposes of selecting preliminary COECs for the site, as discussed in the next section. However, this does not mean that all available data are to be combined. "Appropriateness" of data should take into consideration the area of exposure to be assessed.

An exposure area can be defined as the area in which a receptor will be exposed to a medium through one or more exposure pathways. The boundaries of the exposure area depend on the available pathways for exposure and the habitats potentially exposed to contamination. An exposure area may be the entire site if chemical contamination is widely dispersed, or it may be a small subsection of the site if chemical contamination is localized. The exposure area may be a downwind/downgradient area for air, soil, or surface water exposure. Because the exposure area is a function of receptor foraging range as well as a real extent of contamination, the exposure area may include portions of the site that have not been impacted by specific chemicals that are being assessed. For example, if a former tank area is being assessed within a larger site, soil samples from the general tank area should be considered as a discrete exposure area and should not be combined with other site soils that are remote from the tank area. When unrelated areas of the site are combined with impacted areas, detection frequency and exposure point concentrations can be biased low. It would be appropriate, however, to include samples from within the defined tank area that are reported as nondetected with the contaminated samples from within the same area since these samples are within a defined exposure area. Under some circumstances, however, inclusion of unrelated areas may be acceptable where doing so provides a more realistic foraging-exposure area for a receptor population of concern.

CASE STUDY 5

SAMPLING RESULTS (TERRESTRIAL ECOSYSTEM)

The following soils data were obtained from site sampling.

Soil Sample Location	Acetone (ug/kg)	Arsenic (mg/kg)	Cadmium (mg/kg)	Nickel (mg/kg)	Lead (mg/kg)	Barium (mg/kg)
SS1	5 B	7.8	100	20	4	302
SS2	2 BJ	6.2	92	16	17	314
SS3	5 U	5 U (2.5)	78	19	16	356
SS4	5 B	10.3	75	15	19	396
SS5	5 U	4.9 J	42	12	13	377
SS6	2 BJ	11.4	51	19	15	342
SS7	6 B	5 U (2.5)	33	21	18	309
SS8	3 BJ	7.9	29	17	18	433
SS9	5 U	9.4	53	18	14	395
SS10	3 BJ	5 U (2.5)	48	14	16	302
SS11 (background)	7 B	8.4	32	19	19	392
SS12 (background)	4 BJ	6.2	56	16	13	376

B = Analyte found in associated blank as well as in sample
U = Compound analyzed, but not detected
J = Value is estimated
( ) = Value is 1/2 the sample 9 detection limit

Reference area locations should not be included with site samples when defining an exposure area. Reference locations are selected to represent offsite conditions and to help distinguish chemicals and ecological conditions that are site-related and those that are not. Reference samples may or may not be "clean," depending on local background conditions, global atmospheric deposition, other anthropogenic sources, or upgradient sites (i.e., other non-site-related sources of chemicals may be present), but they should not be impacted by site conditions. Reference samples should be collected from locations unimpacted by anthropogenic inputs, to the greatest degree reasonably possible. Reference areas may be used to establish background chemical concentrations, if appropriate criteria are used to select the reference areas. Further discussion on use of background determinations is presented in Section 4.2.3.3.

4.2.3 Selection of Preliminary Chemicals of Ecological Concern

COECs are those chemicals that can potentially induce an adverse response in ecological receptors. Because not all chemicals found at a site will have adverse effects on biota, the list of chemicals to be evaluated can be narrowed Chemical, physical, ecological, and toxicological criteria are used in evaluating preliminary COECs. COECs typically include: (1) chemicals that are not laboratory contaminants (i.e., chemicals whose detection has not been flagged as a result of laboratory contamination), (2) chemicals that occur at higher concentrations than those found at background or reference sites, (3) chemicats that have the potential (qualitatively based on concentrations detected and toxicity) to cause acute or chronic toxicity following exposure, (4) chemicals which have the potential to bioaccumulate or biomagnify. Although the selection process for COECs parallels that for the human health risk assessment, the lists may differ somewhat based on chemical fate and transport characteristics and species-specific toxicities.

4.2.3.1 Objectives

The objective of selecting preliminary COECs for the Tier I ERA is to identify a subset of chemicals detected at the site that have data of good quality, are not naturally occurring or a result of nonsite sources, and are present at sufficient frequency, concentration, and location to pose a potential risk to ecological receptors. The selection of COECs is a process that considers site-specific chemical data in conjunction with the preliminary ECSM (see Section 4.2.6) that describes potential exposure pathways from chemical sources to ecological receptors. This selection process is needed for several reasons:

- Not all chemicals detected at a site are necessarily related to site activities. Some may be naturally occurring, a result of anthropogenic activities, or a result of chemical use in offsite areas.
- Some chemicals may be a result of inadvertent introduction during sampling or laboratory analysis.
- Disparities as well as similarities exist in the selection process for COECs and chemicals of concern to human health.
- Not all chemicals detected at a site are present at concentrations high enough to pose a potential exposure or ecological threat. Additionally there may be trace elements present at nutritionally required or ecologically protective concentrations.

The chemical selection process is performed by evaluating the data that have been identified as useable by the data evaluation process (described previously). Chemical selection involves evaluation of these data using criteria to identify those chemicals that are not appropriate to retain as COECs (see Section 4.2.3.3). Through an exclusion process, the COECs are selected from the list of chemicals analyzed in site media. The outcome of the selection process is a list or lists of chemicals in site media that will be assessed quantitatively in the ERA.

4.2.3.2 General Considerations

Two general factors should be considered before applying the chemical selection process. These factors allow the assessor to select the most appropriate data to include in the assessment.

What is the exposure area?

- Not all chemical data collected from site media represent those to which ecological receptors are necessarily exposed. When selecting COECs, the potential receptors, exposure pathways, and exposure routes identified in the preliminary ECSM should be examined. The preliminary ECSM will identify how and where exposure is expected to occur (i.e., through soil, sediment, or

water ingestion, by direct contact or indirect ingestion, etc.). This information is then used to help identify the media and locations where assessments will be directed and COECs need to be identified.

- A distributional analysis of the chemicals present at a site should be conducted. This examination would differentiate between impacted areas and nonimpacted areas. The distributional analysis may be a statistical or a qualitative evaluation. The distributional analysis may identify the whole site as the exposure area or only subunits of the site as the exposure area.

Are the chemical data appropriate?

- Even with high quality, useable data, the form of the chemical or sampling technique should be examined for useability and relevance for exposure. Federal AWQC for metals are based on total recoverable metals; measurement of dissolved metals levels would therefore not be directly comparable (although dissolved metals measurements do have a place in ERAs).' Filtered water samples are generally not relevant for most wildlife exposures. To apply Federal AWQC, site-specific factors associated with metals availability (e.g., total organic carbon, pH) and toxicity to aquatic life need to be collected (EPA 1993c).

Are the chemical data ecologically relevant?

- Soil and sediment samples from below a predetermined biologically relevant depth are not typically included in the terrestrial assessment. The biologically relevant depth is based on the ecology of the site and the depth to which small mammals or other receptors of concern (birds or invertebrates) on the site burrow and may therefore be exposed. Feeding habits of animals also determine the type of exposure. Data composited from multiple locations over a large area am not relevant to exposures for animals with a small home range or specific habitat preferences.

[1] EPA has published metals ratios so that comparisons can be made between dissolved and total metals concentrations *(see Water Quality Standards: States Compliance - Revision of Metals Criteria,* Interim Final Rule, 60 FR 22229 [EPA 1995f]).

4.2.3.3 Selection Criteria/Methodology

Criteria that can be applied to determine whether a chemical should be removed as a potential COEC must be fitting to the selected or anticipated ecological endpoints and the overall adequacy of the sampling program. The process for selecting COECs is not entirely standardized or mechanistic, but employs a considerable amount of professional judgment throughout the process. For example, the assessor should consider whether limited chemical distribution or limited presence is an artifact of sampling inappropriate media or locations? Were groundwater wells screened at appropriate locations to detect nonaqueous phase liquids (NAPLs; e.g., coal tars)? Could site-related COECs potentially exert similar toxic action as background "contaminants" or exacerbate the toxicity of the background "contaminants"?[2] The decision to carry forward all detected compounds into the exposure and effects characterization portions of the screening or baseline ERA is sometimes made depending on the number of chemicals detected and project scope.. More often, risk assessors chose to sequentially eliminate chemicals through the progressive application of screening criteria. Through this elimination process, the risk assessor assumes that all chemicals are addressed (not overlooked), but that only the relevant chemicals are carried forward into the quantitative risk analysis. Examples of screening criteria include the following:

- Nondetection (use of appropriate detection limits).
- Limited chemical distribution and limited presence in environmental media.
- Comparability with screening criteria (AWQC, effects range-low (ER-Ls), LELs, etc.).
- Comparability with background concentrations (consideration of site-relatedness).
- Non-site-relatedness.
- Role as an ecologically essential nutrient at site concentrations.
- Low toxicity/bioconcentration screen.

[2] Contaminants, in this case, refers to naturally occurring metals or organics or chemicals present as a result of large, regional-scale contamination.

- Low potential for bioaccumulation and biomagnification.

These criteria, which generally follow *RAGS I and II* (EPA 1989a,f). are typically applied sequentially to the available data Once a chemical is eliminated based on a screening criterion, it is not considered in subsequent screening. Each of the above criterion is discussed further in the following sections. Further explanation of the COEC selection process is provided in CS 6 and CS 7.

The ECSM will often identify two or more ecological receptors of concern, particularly where both terrestrial and aquatic ecosystems are present. In these cases, the COEC selection process is branched: one branch focuses on aquatic receptors, the other branch focuses on terrestrial receptors. Within the terrestrial COEC selection process, further branching may occur in those cases where the chemicals are known to bioaccumulate. Where there are migratory birds and higher trophic level predatory raptors present, for example, one branch would focus on the COECs that may have acute or chronic effects on migratory birds, and the other branch would focus on chemicals that bioaccumulate and may affect the top trophic level receptors (e.g., raptors).

4.2.3.3.1 Nondetection. Chemicals analyzed for but not detected in any sample of a site medium should not be included as COECs for that medium. To be selected, a chemical must be found in at least one sample of the environmental medium at a reported concentration (i.e., the results are not reported as nondetect and qualified with a "U"). To be included, a chemical must have concentrations above the sample quantitation limit (SQL), which is the lowest level that a chemical may be accurately and reproducibly quantified (EPA 1989c), or have concentrations that are quantified but estimated (i.e., less than the SQL and labeled with a "J" qualifier). Where samples have an associated duplicate analysis, the higher of the sample or the duplicate results (if both were detected) is usually presented, if both the sample and the duplicate results were not detected (ND), then the lower of the two SQLs is presented; if one result is detected and the other is ND, then the detected concentration is reported.

Care must be taken when evaluating analytical results in which a very high detection limit is attained, since a nondetection may mask the presence of a chemical at a concentration less than the quantitation limit. Although a quantitative estimate of the chemical's concentration value is unavailable in such a case, the chemical may need to be assessed qualitatively if it is present in other site media

Detection levels also need to be evaluated with respect to ARARs and toxicity screening levels. For some PAHs and dioxins, detection limits below the estimated toxicity effects level for a particular receptor of concern may not be possible. For other chemicals, such as mercury, the detection limit (0.01 pg/L) is barely below the AWQC (0.012 pg/L).

4.2.3.3.2 Chemical Distribution. The physical distribution and frequency of detection of a chemical in a site medium or exposure area can be used to remove a chemical from consideration as a COEC. The premise behind this criterion is that a chemical with limited presence in a medium or exposure area is unlikely to be contacted frequently and, therefore, does not pose as great a potential ecological risk as do more frequently detected chemicals.

The distribution of the chemicals present in a site or exposure area should be examined by identifying where the chemicals were and were not detected and their frequency of detection. If this evaluation indicates that the distribution of a chemical is low, i.e., it is detected in only one or a few locations, it may be reasonable to exclude it as a COEC (assuming an appropriate sampling design was used), or to select the chemical as a COEC for a smaller exposure area of the site. Within the smaller exposure areas, chemicals detected in five percent or fewer samples may also be considered for elimination.

The following factors should be considered when applying this criterion:

- The number of samples available. In a small data set, a limited frequency of detection of a chemical may be more a statistical artifact of a limited sampling design rather that the infrequent presence of the chemical.

- The quantitation limit achieved. If the quantitation limit achieved in one or more of the analyses is high relative to other detected concentrations, the high quantitation limit may mask the presence of chemicals.

- The sampling scheme. Biased sampling plans, intended to identify "hot spots," may over-represent the occurrence of chemicals (however... see the next point).

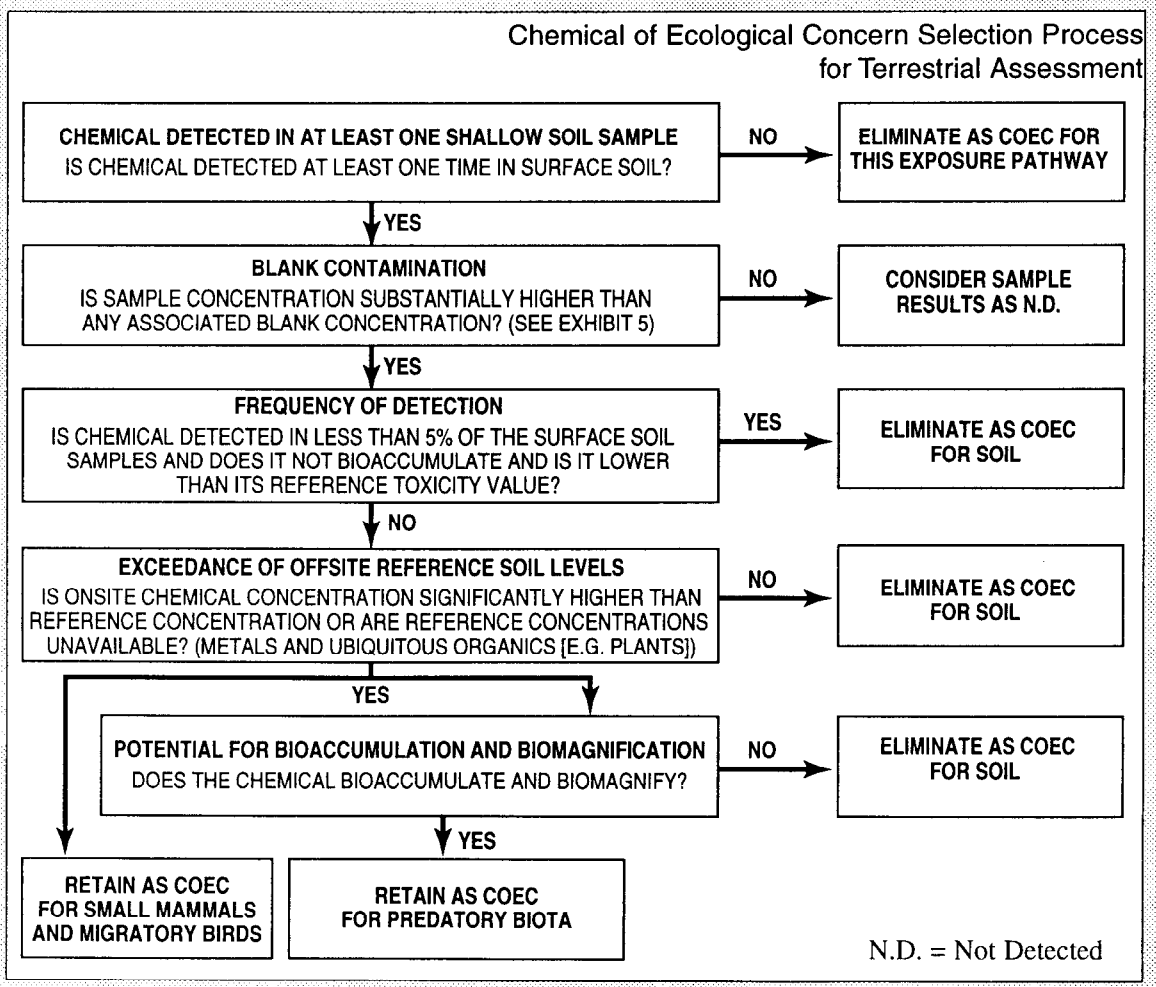
CASE STUDY 6

SELECTION OF COECS - I (TERRESTRIAL ECOSYSTEM)

The chemical data for soil need to be examined to select chemicals of ecological concern, or COECs, for the assessment. Examine the data for soil with respect to the provided information and the following factors:

- Nondetection,
- Comparison with laboratory blanks,
- Limited presence,
- Comparability with background concentrations,
- Non-site-relatedness,
- Role as an essential nutrient,
- Toxicity screen, and
- Potential for bioaccumulation and biomagnification.

Then select the COECs. A flow diagram similar to that shown below may be developed to depict the COEC selection process that is used.



CASE STUDY 7

SELECTION OF COECS - II (TERRESTRIAL ECOSYSTEM)

Now examine the soil data and select soil COECs for the ERA:

Comparison with Laboratory Blanks - Soils

Acetone was detected in several soil samples. There are no field blanks associated with the soil samples, so no direct comparison with field blanks can be made. However, three factors suggest that acetone is not site-related. First, the B qualifier indicates that acetone was detected in the laboratory method blanks and is therefore a laboratory contaminant. Second, acetone was found in background soil samples at concentrations comparable to those in site samples. Third, acetone is volatile and would not be retained in surface soil, suggesting its presence as a laboratory contaminant. For these reasons, acetone is not retained as a COEC (although it is treated as a COEC for the purpose of developing a Reference Toxicity Value [RTV] in CS 12).

Comparison with Background - Soils

A statistical evaluation or a numerical comparison can be used to make background comparisons. In this example, a numerical comparison is used due to the limited number of background samples. Three factors are examined: the range of concentrations detected, the arithmetic mean, and the 95% upper confidence limit (UCL) of the mean concentration (assuming a lognormal distribution). The 95% UCL is calculated only for site data because the background sample size (n = 2) is too small to support statistical estimation of the mean.

	Arsenic	Barium	Cadmium	Nickel	Lead
Site Samples					
Range (mg/kg)	5U-11.4	302-433	2.9-100	12-21	4-19
Arithmetic Mean	6.3	352.6	60.1	17.1	15
95% UCL	10.5	390	81.8	19.2	18
Sample Size	10	10	10	10	10
Background Samples					
Range (mg/kg)	6.2-8.4	376-392	32-56	16-19	13-19
Arithmetic Mean	7.3	384	44	17.5	16
Sample Size	2	2	2	2	2

When ranges of concentrations are compared and mean and 95% UCL site concentrations are compared to background means, arsenic, barium, nickel, and lead appear to be comparable to background; cadmium does not. From this numerical comparison, concentrations of arsenic, nickel, barium, and lead are considered comparable to background concentrations and these metals are therefore not selected as COECs. Cadmium is retained as a COEC for this site.

Examination of Role as Essential Nutrient - Soils

None of the metals detected in surface soils, with the possible exception of arsenic, are essential micronutrients for ecological receptors.

- The concentrations detected. Presence of a chemical at relatively high concentrations, even at a low frequency, may indicate the occurrence of a localized area of contamination (i.e., a hot spot) that may need to be examined as a discrete exposure area, and may require further sampling. What constitutes a "high" or a "low" concentration depends upon the toxicity and other properties of the chemical, the medium in which it was detected, and the site history (whether the chemical was used at the site), and requires some degree of professional judgment to identify.

4.2.3.3.3 Comparability with Background Concentrations. In conducting a risk assessment, it may be important to distinguish site contamination from background levels due to anthropogenic or naturally occurring contamination in order to determine the presence or absence of contamination and to compare with background risk (EPA 1992d,e). Some chemicals detected in site media may be naturally occurring or present as a result of ubiquitous or offsite chemical use. Therefore, it is appropriate to exclude them from the risk assessment. Exhibit 6 presents some chemicals that should be examined for presence in background samples. Background samples are kept discrete from the site data for the purposes of assessing exposures, and are used exclusively to identify non-site-related chemicals.

The most appropriate measure of background quality is obtained by the collection of background data from unaffected onsite areas or nearby, offsite areas, or reference areas. The risk assessor should be involved in the selection of background sample numbers, types, and locations as part of the ERA minimum data requirements, to ensure that adequate data are collected. When selecting COECs, the background data collected should be reviewed to identify whether minimum requirements have been met, or in the case of historical data, whether background measurements are adequate. The following factors should be considered.

Are the locations of the background samples appropriate?

. Appropriate background sampling locations vary with the media being examined, but should generally be offsite; hydrologically upgradient for surface water and sediments: upwind of the site at the time of measurement and under usual climate conditions for air; and in areas remote from surface water drainage for soil. Background samples should also be located away from other potential offsite sources of contamination that would not impact the site, such as other sites, roadways, etc.

- If offsite areas have the potential to contribute chemicals to the site being assessed (for example, upgradient industrial facilities), part of the goal of identifying appropriate background sample locations should be to obtain sufficient background samples to identify potential chemical contributions from offsite sources.

Are the background samples comparable in type to the media being examined?

- Background samples should be as similar as possible to the site samples being evaluated. Background sampling locations should have similar habitat and soil conditions to the onsite locations. Soil and sediment depths and stream characteristics should be comparable. The type of analyses performed on site and background samples (such as filtered versus unfiltered water, soluble versus total metals) should also be comparable.

Are the number of background measurements sufficient?

- Erroneous conclusions may be drawn if the number of background samples collected is insufficient to adequately describe background. The number of background samples should be specified as a minimum requirement during the project planning stage. The actual number of samples with data available should be examined to determine if the minimum requirements have been met. For historical data, professional judgment must be used to determine whether adequate background samples are available, or if additional samples are required.

- Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between sample mean and the 95% UCL), while data sets with 10 to 20 samples per exposure area provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95% UCL is close to the sample mean) (EPA 1992h). In general, the UCL approaches the true mean as more samples are included in the calculation.

Acquisition of site-specific background information is always preferable to regional or national values when examining site-relatedness and comparability to background concentrations. Literature values describing regional or national background ranges for chemicals in soil, groundwater, surface water, and sediments may be used, but only if site-specific background is unavailable. Regional or national ranges are relatively insensitive and can lead to the erroneous exclusion of a chemical as a COEC. If historical data include NPDES data, they may be used in addition to any other regulatory-required data acquisition.

Determination of comparability with background can be accomplished in several ways, depending on the amount of data available. Two methods that are available are statistical evaluation and numerical comparison.

A statistical evaluation is best when enough site and background samples are available to test the null hypothesis that there is no difference between the site and background mean chemical concentration at a defined level of confidence. This approach can be used when the risk assessor has defined the minimum requirements for background and site sample numbers and sampling design.

Several statistical tests are available with which to determine whether the two data groups, background and site, are comparable. Texts on statistics, such as Zar (1984), Ludwig and Reynolds (1988), or Gilbert (1987), should be consulted for tests applicable for use in specific site conditions. Test selection depends upon data distribution (normal, non-normal), whether nondetected values are included, if appropriate proxy values are used, number of samples, and other factors. This is the most rigorous method of determining comparability. An example of one type of statistical comparison that assumes a normal distribution of data with two unequal variances is shown in CS 8.

Numerical comparisons can be made when background data are more limited in number, making a statistical comparison less meaningful. This approach may be useful when historical data with limited background samples are being used, or when minimum requirements for ERA data collection have not been met and less than optimal numbers of background sample results are available. The following comparisons can be made:

- Comparison of site and background arithmetic mean concentrations.
- Comparison of site and background 95% UCL concentrations.
- Comparison of range of detected concentrations in both data sets.

For the most thorough comparison, all three of these factors should be examined. In a numerical comparison, the definition of "comparability" is arbitrary. Selecting a factor, such as a factor of two, while arbitrary, provides a benchmark against which to define comparability. As an example of this approach, site samples could be defined as comparable if the mean concentration were less than or equal to two times the mean background concentration.

4.2.3.3.4 Determination of Site-Relatedness. Background sampling is conducted to distinguish site-related contamination from naturally occurring or other non-site-related levels of chemicals (EPA 1989f). In some instances, comparison with background is insufficient to identify chemicals that are derived from other sources, despite appropriate planning of background sample locations. If such chemicals are not site-related, however, they generally should not be included in the ERA, although this decision requires professional judgment for reasons noted earlier (Section 4.2.3.3) and policy[3] considerations. If adequate and confirmable information is available that identifies a different site as the source of a chemical, even in the absence of background information, it may be appropriate to exclude that chemical as a COEC. The supporting information must be conclusive and presented in the report.

4.2.3.3.5 Trace Element and Essential Nutrient Status. Some chemicals are essential trace elements or nutrients in the diet of plants or animals, and may be present in site media at nutritionally required concentrations or ecologically protective levels. The following chemicals can be evaluated with regard to essential trace element or nutrient status:

[3] Recent court cases, plus policies adopted by some states, suggest that "non-site-relatedness" is not an appropriate criterion: mere presence of a potential COEC may require a response, while the assessment or assignment of liability for that response must be determined separately and is not to interfere with the response assessment.

CASE STUDY 8

EXAMPLE OF APPLYING A STATISTICAL TEST TO DETERMINE COMPARABILITY WITH BACKGROUND

Data Set:

Site Samples	Background Samples
$x_1 = 125$	$x_2 = 97$
$s_1 = 50.6$	$s_2 = 26.9$
$n_1 = 40$	$n_2 = 8$

Assumptions: If the data for the analyte are normally distributed or can be log-transformed to become normal, the Student's t-test is used. If the data are neither normal nor log-normal, then a nonparametric test such as the Mann-Whitney U test is used.

The distribution of the results suggested that both the site and background data are normally distributed. The population variances are unknown but assumed to be unequal.

Hypothesis: The null hypothesis is

$$H_0: \mu_1 \leq \mu_2$$

The alternative hypothesis is

$$H_a: \mu_1 > \mu_2$$

Procedure: The calculations are conducted assuming unequal variances between the two data sets. This assumption generally holds true for environmental data sets but will not impact the results if the variances are equal. The test results include a calculated t parameter and degrees of freedom (df). The calculated t is compared to the critical t (assuming a significance level of a = 0.01) to assess if the null hypothesis is rejected. The nondetects may be treated as follows: (1) for those data sets with more than 85 percent of detects, the nondetects are replaced by 1/2 of the SQL, and (2) for those data sets with 30 to 85 percent detects, Aichison's Adjustment may be performed before the t parameter is calculated to account for the nondetects in the data sets. The Aichison's adjustment procedure is explained in greater detail in the *Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities* (EPA 1989g). If 30 percent or fewer of the samples have detectable concentrations, then tests such as the Poisson Tolerance Limits (PTL) are used.

Statistic:

$$t = \frac{(x_1 - x_2) - (\mu_1 - \mu_2)}{(s_p^2/n_1 + s_p^2/n_2)^{0.5}}$$

x = mean concentration of the sample set (mg/kg)
s = standard deviation (mg/kg)
n = sample size
μ = true mean of the population
s_p^2 = pooled sample variance

Using this method, the sample variances are pooled by the following equation:

$$s_p^2 = \frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}$$

$$s_p^2 = \frac{(40 - 1)(50.6)^2 + (8 - 1)(26.9)^2}{40 + 8 - 2}$$

$$s_p^2 = 2{,}281$$

Distribution of Test Statistic: If the null hypothesis is true, the test statistic follows the Student's t distribution with v′ degrees of freedom.

$$v' = \frac{\left[\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}\right]^2}{\frac{(s_1^2/n_1)^2}{n_1 - 1} + \frac{(s_2^2/n_2)^2}{n_1 - 2}} = \frac{\left[\frac{(50.6)^2}{40} + \frac{(26.9)^2}{8}\right]}{\frac{(50.6^2/40)^2}{40 - 1} + \frac{(26.9^2/8)^2}{8 - 1}}$$

v′ = the adjusted degrees of freedom and the standard t distribution table can be used.

$$s_p^2 = \frac{\sqrt{s^2}(n_1 + n_2)}{n_1 * n_2}$$

Decision Rule: Fail to reject (accept) the null hypothesis if $t > 1.684$.

Accept (or fail to reject) the alternative hypothesis if t does not exceed 1.684.

Calculation:

$$t = \frac{(125 - 97) - (0)}{\left[\frac{2281}{40} + \frac{2281}{8}\right]^{\frac{1}{2}}} = 1.51$$

Decision: The calculated t value does not exceed 1.684. Therefore the null hypothesis must be rejected, and the alternative hypothesis is not rejected (i .e., that site concentrations exceed background concentrations).

- Calcium.
- Copper.
- . Chromium (trivalent).
- . Magnesium.
- [illegible]
- Iron.
- Potassium.
- Selenium.
- Sodium.
- [illegible]

Elements that serve as nutrients and are within the recommended allowable dietary range for some receptors may be toxic to other ecological receptors at the same concentration (McDowell 1992). For example, metals such as copper may not be toxic to animals which drink the water, but may be toxic to aquatic organisms. The toxicity of such chemicals should be evaluated in light of the potential site-specific receptors. As a general screening tool, the nutritional requirements of domestic animals (mammals and birds) can be used to assess whether site concentrations of these elements are within acceptable ranges or are likely to pose a hazard to onsite receptors. Nutritional requirements and limits for livestock and experimental laboratory animals (e.g., small mammals, birds, fish) are well-established.

The evaluation of chemicals as trace elements or dietary requirements may be made on a qualitative or quantitative basis. Elements such as calcium, iron, magnesium, potassium, and sodium are rarely retained as COECs, for example. It should be noted in any case, however, whether the elements could be present at a site as a result of site activities. If it is known that a particular element's occurrence is a result of site activities, it may not be appropriate to remove it from the list of COECs.

4.2.3.3.6 Preliminary Toxicity Screen

A toxicity screen to determine which chemical concentrations exceed applicable regulatory standards (toxicity benchmarks) is performed for the selection of COECs. Various reference toxicity values for water and sediment developed by EPA (1986b, 1993b, 1994e, 1995b,f) can be used. ORNL (1994) has also developed screening benchmark preliminary values for aquatic and terrestrial ecosystems.[4] Guidance values from NOAA (Long and Morgan 1990), Washington State Department of Ecology (1991) Florida Dept. of Environmental Protection (MacDonald 1994), and Canada (Long et al. 1995, Persaud, Jangumagi, and Hayton 1992, CCME 1995) for marine and freshwater sediment threshold environmental effects levels can be used directly in Tier I screening for COECs in aquatic ecosystems with few or no modifications (see Exhibit 7). Additional toxicity benchmarks for aquatic ecosystems may be developed using information provided in EPA databases such as ECOTOX and ASTER (see Appendix B, Information Sources).

Standardized values to perform a toxicity screen of chemicals in terrestrial ecosystems are generally not available, although ORNL (1994) has recently published toxicity benchmarks for a variety of benchmarks that can be used in a Tier I terrestrial toxicity screen. Standardized values for screening terrestrial wildlife are currently under development by EPA. Four water quality criteria (mercury, p,p'-dichlorodiphenyl-trichloroethane [DDT], 2,3,7,8-tetrachlordibenzo-p-dioxin [TCDD], and polychlorinated biphenyls [PCBs]) for the protection of wildlife (birds and mammals) which feed on aquatic organisms are published in the GLWQI Final Rule (EPA 1995b). In a few cases, chronic Federal AWQC for chemicals that bioaccumulate are based on final residue values and the protection of sensitive mammals (PCBs and mink) or birds (DDT and brown pelican). Where such exposure pathways are appropriate, the GLWQI criteria and Federal and state AWQC should be used in screening water concentrations for COEC selection. A cautious approach should be used in COEC screening as toxicity can differ among similar receptor species due to differences in either physiology or exposure. For example, some songbirds seem to be more sensitive to organophosphorus compounds than other songbirds (personal communication, Dr. J. Whaley, USACHPPM, 1995).

[4] The ORNL (1994) benchmark values are a useful preliminary screening tool. However, these documents do contain errors, have yet to be widely peer-reviewed, and should not be considered standardized benchmarks. ORNL will be updating these benchmarks and posting them on the Internet (www.ornl.gov).

In terrestrial ecosystems, chemicals may be very limited in distribution, but still present potential for acute toxicity for ecological receptors. For those chemicals that are found at limited locations or in 5 percent or fewer samples and tend not to bioaccumulate, the lethal concentration for 50 percent of the population (LC_{50}) values (for plants or soil-dwelling organisms) may be compiled from available ecotoxicological literature and compared to the 95th UCL concentration in soil. The concentration term for each chemical in soil is the lower of (1) the maximum detected concentration or (2) the 95% UCL of the mean (see Section 4.3.3).

Chemicals that have the potential to bioaccumulate or biomagnify through the food web should be retained for consideration as COECs, even where distribution is limited or they might be eliminated based on the preliminary toxicity screen. Chemicals that bioaccumulate include those that are taken up by an organism either directly from exposure to a contaminated medium or by consumption of food containing the chemicals (Rand and Petrocelli 1985). Chemicals that biomagnify are those that are found in increasingly higher tissues concentrations in higher trophic levels (i.e., concentrations increase across at least two trophic levels) (EPA 1995b). By definition, chemicals that tend to biomagnify also bioaccumulate. Chemicals with a log K_{ow} of less than 3.0 or a K_{oc} of less than 500 (i.e., log K_{oc} less than 2.7) are not expected to bioaccumulate or biomagnify. A lengthy list of bioaccumulative (biomagnify) and nonbioaccumulative chemicals that are of potential concern is presented in the GLWQI (EPA 1995b)[5] (see Table 4-l).

The chlorinated pesticides are the most well known of the chemical groups that tend to bioaccumulate and biomagnify. PCBs and dioxins/furans are also strong bioaccumulators and biomagnifiers. Volatile organic compounds (VOCs) such as tetrachloroethene, toluene, trichloroethene, 1,l,1-trichloroethane, and xylenes are unlikely to bioaccumulate and biomagnify (Van Leeuwen et al. 1992; EPA 1982). Semivolatiles, including PAHs, tend not to bioaccumulate and show little tendency to biomagnify because they are readily metabolized (Eisler 1987, Beyer and Stafford 1993).

4.2.3.4 Presentation of Chemicals of Ecological Concern

The chemical selection process results in a select list of preliminary COECs that will be quantitatively assessed in the ERA. Tables should be developed identifying the COECs selected for each medium and/or exposure area. All chemicals that were removed from consideration should be identified, with an explanation of the reason for the removal. A flow diagram illustrating the COEC selection process should be included to clearly illustrate the decision process used (CS 6).

4.2.4 Selection of Key Receptors

Receptors are the components of ecosystems that are or may be adversely affected by a chemical or other stressor. Endpoints are characteristics of an ecological component that may be affected by an environmental stressor (e.g., chemical contaminant) (EPA 1992a). Because it is difficult to assess potential impacts to all receptors for all endpoints, ecological assessment methods select particular types of receptors (key receptors) and endpoints (see Section 4.2.5) to represent potential harm to all components of the system.

4.2.4.1 Objectives

Grouping of species, organisms, habitats, or ecosystem components under the heading of key receptors helps focus the exposure characterization portion of the Tier I ERA on species or components that are the most likely to be affected and on those that, if affected, are most likely to produce greater effects in the onsite ecosystem. The focus of the receptor selection process is on species, groups of species (e.g., birds, benthic invertebrates), or functional groups (feeding guilds), rather than higher organizational levels such as communities or ecosystems. Chemical-specific toxicological input parameters are also generally limited to the more common organisms or species in the onsite environment and prey organisms that are likely to be used more heavily than others. Although grouping species together for the purposes of exposure and risk quantitation (model analysis) results in some error of uncertainty, this error might be offset by the use

[5] The GLWQI table is based on chemicals that bioaccumulate and are of initial concern in the Great Lakes because of their strong tendency to biomagnify. Chemicals listed in this table as "'not of concern" are still of considerable concern due to their bioaccumulation potential. Chemicals that bioaccumulate in lower level organisms may still present a significant contaminant pathway and dietary hazard to higher trophic level receptors, even if they don't biomagnify in the latter. For example, copper is bioaccumulated to very high level by oysters, but does not biomagnify through food webs. PAHs are accumulated in invertebrates which lack metabolic pathways for their excretion, yet am not accumulated in most vertebrates which have such enzyme systems.

Table 4-I
Chemicals of Ecological Concern According to Final Water Quality Guidance for the Great Lakes System (EPA 1995b)

Pollutanta that an bioaccumulative chemical of concern (BCCs)
Chlordane
p,p'-dichlorodiphenyl-trichloroethane (DDT) and metabolites
4,4'-DDD; p,p'-DDD; 4,4'-TDE; p,p'-TDE
4,4'-DDE; p,p'-DDE
4,4'-DDT; p,p'-DDT
Dieldrin
Hexachlorobenzene
Hexachlorobutadiene; hexachloro-1,3-butadiene
Hexachlorocyclohexanes (HCH); BHCs (benzene hexachloride; synonym for HCH)
alpha-Hexachlorocyclohexane
beta-Hexachlorocyclohexane
delta-Hexachlorocyclohexane
Lindane; gamma-BHC; gamma-hexachlorocyclohexane
Mercury
Methoxychlor
Mirex; dechlorane
Octachlorostyrene
PCBs; polychlorinated biphenyls
Pentachlorobenzene
Photomirex
2,3,7,8-TCDD; dioxin
1,2,3,4-Tetrachlorobenzene
1,2,4,5-Tetrachlorobenzene
Toxaphene
Pollutants that are not bioaccumulative chemicals of concern*
Acenaphthene
Acenaphthylene
Acrolein; 2-propenal
Acrylonitrile
Al&in
Aluminum
Anthracene
Antimony
Arsenic
Asbestos
1,2-Benzanthracene; benz[a]anthracene
Benzene
Benzidine
Benzo[a]pyrene; 3,4-benzopyrene
3,4-Benzofluoranthene; benzo[b]fluoranthene
11,12-Benzofluoranthene; benzo[k]fluoranthene
1,2-Benzoperylene; benro[ghi)perylene
Beryllium
Bis(2-chloroethoxy)methane
Bis(2-chloroethyl) ether
Bis(2-chloroisopropyl) ether
Bromoform; tribromomethane
4-Bromophenyl phenyl ether
Butyl benzyl phthalate
Cadmium

Table 4-1 (Continued)

Pollutants that are not bioaccumulative chemicals of concern*

Carbon tetrachloride; tetrachloromethane
Chlorobenzene
p-Chloro-m-cresol; 4-chloro-3-methylphenol
Chlorodibromomethane
Chloroethane
P-Chloroethyl vinyl ether
Chloroform; trichloromethane
P-Chloronaphthalene
2-Chlorophenol
4-Chlorophenol phenyl ether
Chlorpyrifos
Chromium
Chrysene
Copper
Cyanide
2,4-D; 2,4-Dichlorophenoxyacetic acid
DEHP; di(2-ethylhexyl) phthalate
Diazinon
1,2:5,6-Dibenzanthracene; dibenz[a,h)anihracene
Dibutyl phthalate; di-n-butyl phthalate
1,2-Dichlorobenzene
1,3-Dichlorobenzene
1,4-Dichlorobenzene
3,3'-Dichlorobenzidine
Dichlorobromomethan; bromodichloromethane
1,1-Dichloroethane
1,2-Dichloroethane
1,1-Dichloroethylene; vinylidene chloride
1,2-trans-Dichloroethylene
2,4-Dichlorophenol
1,2-Dichloropropane
1,3-Dichloropropene; 1,3-dichloropropylene
Diethyl phthalate
2,4-Dimethylphenol; 2.4-xylenol
Dimethyl phthalate
4,6-Dinitro-o-cresol; 2-methyl-4,6-dinitrophenol
2,4-Dinitrophenol
2,4-Dinitrotoluene
2,6-Dinitrotoluene
Dioctyl phthalate; di-n-octyl phthalate
1,2-Diphenylhydrazine
Endosulfan; thiodan
alpha-Endosulfan
beta-Endosulfan
Endosulfan sulfate
Endrin
Endrin aldehyde
Ethylbenzene
Fluoranthene
Fluorene; 9H-fluorene
Fluoride
Guthion
Heptachlor

Table 4-1 (Concluded)

Pollutants that are not bioaccumulative chemicals of concern*
Heptachlor epoxide
Hexachlorocyclopentadiene
Hexachloroethane
Indeno[1,2,3-cd]pyrene; 2,3-o-phenylene pyrene
Iron
Isophorone
Lead
Malathion
Methoxychlor
Methyl bromide; bromomethane
Methyl chloride; chloromethane
Methylene chloride; dichloromethane
Naphthalene
Nickel
Nitrobenzene
2-Nitrophenol
4-Nitrophenol
N-Nitrosodimethylamine
N-Nitrosodiphenylamine
N-Nitrosodipropylamine; N-nitrosodi-n-propylamine
Parathion
Pentachlorophenol
Phenanthrene
Phenol
Pyrene
Selenium
Silver
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
Thallium
Toluene; methylbenzene
1,2,4-Trichlorobenzene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichloroethylene; trichloroethene
2,4,6-Trichlorophenol
Vinyl chloride; chloroethylene; chloroethene
Zinc

Source: EPA. 1995b. Great Lakes Water Quality Initiative Methodology for Development of Bioaccumulation Factors. Final Rule. Federal Register. Vol. 60. No. 56. March 23.

* Pollutants that are not bioaccumulative (or biomagnifying) chemicals of concern may still be COECs.

of conservative criteria to select key receptors with the greatest sensitivity (highest trophic level receptor or chemically sensitive) or greatest opportunity for exposure.

4.2.4.2 General Considerations

The selection of key receptors is in part a subjective decision based on species presence, dominance, judged importance in the food chain, and societal or scientific value. Key receptors and assessment endpoints are not only species, but may include habitat or areas of special legal protection. Location-specific ARARs, identified as part of the RI effort, may concern locations of natural resources, sensitive ecological receptors, or species protected under a number of resource protection statutes. Some of these statutes were developed several decades ago, and their requirements are very specific. A list of these statutes and the ecological receptors they are designed to protect is presented in Table 4-2. Environmental statutes such as the ESA, Migratory Bird Treaty Act, Eagle Protection Act, and Wetlands Protection Act are used in conjunction with other criteria to help identify (but not mandate) important receptors and select appropriate ecological endpoints (see Exhibit 8). These laws may also be applied to risk management decision-making during the FS/CMS to evaluate the need for and extent of remediation and the potential effects of various remedial alternatives, based on risk characterization performed in the ERA.

Primary criteria for key receptor selection generally include consideration of the following:

- Likelihood of contacting chemicals.
- A key component of ecosystem structure or function (e.g., importance in the food web, ecological relevance).
- Listing as rare, threatened, or endangered by a governmental organization; or critical habitat for such.
- Sensitivity to chemicals.
- Recreational or commercially valued species (e.g., game and livestock).

Additional criteria used in key receptor selection include habitat preference, food preference, and other behavioral characteristics which can determine population size and distribution in an area or significantly affect exposure potential. Key receptors may include mobile game species with large home ranges: or smaller nonmigratory species; or organisms that are sedentary or have a more restricted movement. For chemicals that bioaccumulate, the effects are usually most severe for organisms at the top of the food chain (e.g., top predators) like bass in aquatic ecosystems or raptors in terrestrial ecosystems.

4.2.4.2.1 Likelihood of Contacting Chemicals. Data from the site reconnaissance, biota checklist (if available), and other available literature are used to compile a candidate list from which preliminary key receptors are selected. General field guides and publications on local and regional fauna, including environmental impact statements, provide good preliminary information. Regional natural resource agencies, such as state fish and wildlife departments, should be consulted for more detailed information. Site maps should be reviewed for information on general physiography, ecosystems, and habitat types.

Potential key receptors should be evaluated with respect to their likelihood for directly or indirectly contacting areas affected by chemical input. Key receptor selection analysis includes an evaluation of the receptor's relation to potential COEC exposure through both direct contaminant accumulation from the abiotic environment and bioaccumulation through the food chain. Habitat destruction and loss or absence of the receptor from impacted habitats are additional considerations in selecting key receptors.

Where sites are large and numerous species are likely to be present, the preliminary receptors may be reduced into categories (e.g., small birds, small mammals, wading birds, semiaquatic mammals) or into groups of species that are more toxicologically sensitive (i.e., demonstrate adverse effects to lower environmental concentrations of the COECs). The list may also be reduced by grouping species into taxonomically related groups and/or feeding guilds, such as hawks or eagles that are often top predators in terrestrial food webs. From the reduced list, representative species can be determined on the basis of observations indicating which species are common onsite and potentially most sensitive to the COECs.

4.2.4.2.2 Sensitivity to Chemicals. Species differ in the ways that they take in, accumulate, metabolize, distribute, and excrete contaminants. Susceptibility of an organism also varies with the manner in which organisms am exposed to chemicals in their environment. When possible, key receptors and endpoints arc selected by identifying those that are known to be susceptible to chemicals at the site based on published literature This process

Table 4-2
List of Environmental Laws and Ecological Receptors (Adopted from the revised Hazard Ranking System (rHRS), 55 FR 51624, December 14,1990)

Ecological Receptors to be Protected	Statutory/Regulatory References
Critical habitat for Federal designated endangered or threatened species	Critical habitat as defined in 50 CFR 424.02; The Endangered Species Act Amendments of 1978
Marine Sanctuary	Marine Mammal Protection Act of 1972; Marine Protection, Research, and Sanctuary Act of 1972
National Park	National Park and Recreation Act of 1978
Designated Federal Wilderness Area	Endangered American Wilderness Act of 1978
Areas identified under Coastal Zone Management Act	Areas identified in State Coastal Zone Management plans as requiring protection because of ecological value; Coastal Zone Management Act Amendments of 1976
Sensitive Areas identified under National Estuary Program or Near Coastal Waters Program	National Estuary Program study areas (subareas within estuaries) identified in Comprehensive Conservation and Management Plans as requiring protection because they support critical life stages of key estuaries species under Section 320 of the Clean Water Act; near Coastal Waters as defined in Section 104(b)(3), 304(1), 319, and 320 of the Clean Water Act of 1977
Critical areas identified under the Clean Lakes Program	Clean Lakes Program critical areas (subareas within lakes, or in some cases entire small lakes) identified by State Clean Lake Plans as critical habitat (Section 314 of the Clean Water Act of 1977)
National Monument	Use only for migration pathway
National Seashore Recreational Areas	
National or State Wildlife Refuge	National Wildlife Refuge System Administration Act of 1966
Unit of Coastal Barrier Resource System	
Coastal Barrier (undeveloped)	
Federal land designated for natural ecosystems	National Forest Management Act of 1976
Administratively Proposed Federal Wilderness Area	
Spawning areas critical for the maintenance of fish/shellfish species within river, lake, or coastal tidal waters; Fishery Conservation and Management Act of 1976;	Limited to areas described as being used for intense or concentrated spawning by a given species
Migratory pathways and feeding areas critical for maintenance of anadromous fish species within river reaches or areas in lakes or coastal tidal waters in which fish spend extended periods of time	Anadromous Fish Conservation Act of 1965
Terrestrial areas utilized for breeding by large or dense aggregations of animals	For the air migration pathway, limited to terrestrial vertebrate species. For the surface water migration pathway, limited to terrestrial vertebrate species with aquatic or semiaquatic foraging habitats; Tule Elk Preservation Act of 1965;
National river reach designated as recreational	National Wild and Scenic River System of 1968
Bald and Golden Eagle	Bald Eagle Act of 1940

ensures that a conservative approach is taken to evaluate receptors (at the individual/population, community, or ecosystem level) and endpoints likely to be adversely affected in combination with the potentially most hazardous chemicals found at the site.

4.2.4.2.3 **Threatened and Endangered Species.** By definition, endangered and threatened species are already at risk of extinction; the loss of only a few individuals from the population may have significant consequences for the continued existence of the species. While threatened and endangered species and/or habitats critical to their survival may not necessarily be an important functional component of the ecosystem, they are generally selected as key receptors due to their significant social and scientific value. If a species is rare, but not legally designated as either threatened or endangered, local ecologists or other experts should be consulted to determine the importance of the species in the context of the site. Migratory birds may also require special consideration (see Exhibit 8).

Federal and state natural resource trustees or other specialists should be consulted to determine the location of such species and their potential for exposure to the COECs. The major sources of information on rare, threatened, and endangered species are field offices of the USFWS and NOAA, officials of state fish and game departments and natural heritage programs, and local conservation officials and private organizations.

4.2.4.2.4 **Importance of the Food Web. The** putpose of determining the food web is to evaluate pathways from chemicals in soil, sediment, or water to the affected species. Food web analysis is most important where toxicological data indicate that the COECs bioaccumulate or if the direct effects on organisms from COECs might alter population levels of one or more species. Food webs for many sites can be quite complex. Diagramming the complete food web, however, is rarely reasonable nor necessary. Based on the preliminary list of important species at the site, a preliminary simplified food web can be drawn (see **Section 4.2.6).**

4.2.4.2.5 Food Web Construction. Food web construction requires general knowledge on the food habits of species or species groups (e.g., waterfowl, grasshoppers, zooplankton) potentially occurring on the site. Available data on feeding relationships, such as the percent contribution of a prey species in the diet of a predator, can be included to indicate the strength of the feeding relationship.

Depending on the particular site conditions, one may construct either one or more simple food chains, a community food web, a sink food web, or a source food web (Fordham and Reagan 1991). A food chain would be used to illustrate the movement of chemicals through a series of organisms by progressive consumption. A community food web includes the feeding relations of the entire community. A source food web includes a designated food source (e.g., a particular plant species), all of the organisms that consume the source, and all the species that consume these organisms up to the highest trophic levels involved (Cohen 1978). A sink food web is also a subset of the community food web and includes all the types of organisms eaten by a designated sink species (e.g., bald eagle), the food of these organisms (e.g., fish and small mammals), and so on to the lowest level of the food web (e.g., primary producers) (Cohen 1978). Sink food webs are especially important where threatened and endangered species are a designated key receptor and the pathways by which chemicals biomagnify through various trophic levels to this receptor are to be quantified.

4.2.4.2.6 Keystone Species. Species that may not appear to be important may nevertheless play significant roles in the stability of an ecosystem. Certain rodents (kangaroo rats, prairie dogs) in the arid southwest, for example, are considered keystone species due to their importance as prey for predators, their practice of managing vegetation in such a way as to control species presence, and their importance in providing habitat for other species like burrowing owls. Certain insect groups (both aquatic and terrestrial) may also be regarded as keystone species because of their importance as prey for a wide variety of receptors, the profound effects they can have on vegetative communities, and their potential importance as vectors for contaminant transport. Because of the specialized knowledge required to recognize keystone species and other important receptors, ecologists play a central role throughout the design and conduct of the ERA.

4.2.4.2.7 Reptiles and Amphibians. The selection of reptiles and amphibians as key receptors should be considered, particularly for installations where there are state or Federally protected species. Consideration of reptiles and amphibians has generally been avoided in ERAs due to limited knowledge about contaminant effects on these taxa. Information on contaminant toxicity and population modeling techniques, particularly for frogs and turtles, however, is becoming more prevalent in the published literature and accessible databases. USACHPPM is currently doing extensive exposure and toxicity modeling for

amphibians.[6] Where scope is limited in an ERA, EPA (1986c) suggests one means for evaluating reptiles and amphibians is to assume that when birds and mammals are protected via the risk criteria of the assessment, then reptiles and amphibians are also protected. While some protection is afforded reptiles and amphibians by these same criteria, the level of protection is not known. As more toxicological information becomes available on such organisms, it should be considered more accurately in the ERA.

Reptiles and amphibians should not be ignored in constructing food webs, particularly where chemicals are known to bioaccumulate. Amphibians and reptiles may carry substantial organochlorine residue burdens due to life history factors, particularly feeding habits. Toads, for example, feed primarily upon insects and other invertebrates, while garter snakes use mainly earthworms, salamanders, toads, and mice (Jorschgen 1970). Amphibians and reptiles in turn are a vital dietary component for a highly visible ecosystem component, the raptors (Ross 1989). Snapping turtles were selected as a key receptor in both the ERA and Human Health Risk Assessments at Aberdeen Proving Ground, Maryland.

4.2.4.2.8 Recreationally and Commercially Valued Species. EPA (1989a) suggests that potential adverse effects be noted on species that are of recreational and commercial importance (e.g., sport fish, game), although as key receptors they may not be ecologically relevant. Species that are food sources and directly support these important species, as well as habitats essential for their reproduction and survival, should also be considered in the planning and assessment process.

Information on which species are of recreational or commercial importance in an area can be gathered from state environmental or fish and wildlife agencies, Federal agencies such as NOAA, USFWS, USFS, and local conservation and fish and game personnel. Commercial fishermen's and trappers' associations may also be valuable sources of data.

[6] Mr. Mark Johnson at USACHPPM is specifically conducting research on the effects of munitions on salamanders. He may be contacted at (410)-671-5081 for further information. Mr. Keith Williams at (410)-671-2953 and Mr. John Paul at (410)-6714567, also of USACHPPM, may be contacted regarding their research on munitions and snapping turtles at Aberdeen Proving Ground.

4.2.5 Ecological Endpoints Identification

Ecological endpoints are identified within the ERA process to provide a basis for characterizing risks to the environment. Ecological endpoints are the particular types of actual or potential impacts a chemical or other environmental stressor has on an ecological component (typically a key receptor). These endpoints are of two types:

- Assessment Endpoints. Explicit expressions of the environmental values that are to be protected (EPA 1992a).
- Measurement Endpoints. Measurable responses related to the valued characteristics chosen as assessment endpoints (EPA 1992a).

ERAs typically address both assessment and measurement endpoints. Assessment endpoints are the ultimate focus in risk characterization and the link to the risk management process (EPA 1992a). Assessment endpoints most often describe the environmental effects that drive decision-making, such as reduction of key populations or disruption of biological community structure (EPA 1989a).

Selected assessment endpoints should focus on identifiable harm that may come to exposed receptors. Such harm includes death or reproductive impairment. Appropriate measurement endpoints should also focus on determining which pathways may be complete for site COECs and receptors. As in the PA/SI, measurement endpoints in the Tier I ERA are frequently based on toxicity values from the available literature. In higher tiers, measurement endpoints are more often expressed as the statistical or arithmetic summaries of the actual field or laboratory observations or measurements (EPA 1992a).

When possible, receptors and endpoints are concurrently selected by identifying those that are known to be adversely affected by chemicals at the site based on published literature. COECs for those receptors and endpoints are identified by &awing on the scientific literature to obtain information on potential toxic effects of site chemicals to site species. This process ensures that a conservative approach is taken to selecting endpoints and evaluating receptors that are likely to be adversely affected by the potentially most toxic chemicals at the site.

4.2.5.1 Assessment Endpoints

Most ecological assessment methods focus on population measures as endpoints, since population responses are more well-defined and predictable than are community and ecosystem responses. The latter responses are often more difficult to measure and interpret, highly variable, and not diagnostic of actual exposure. Population measures can also be used to model changes at the community or ecosystem level. Where the population is protected and individuals are important to the overall sustained success of the population, then assessment endpoints focus on adverse effects at the individual level.

Assessment endpoints are identified by drawing on the scientific literature to obtain information on the potential adverse effects of site conditions to populations, communities, and ecosystem levels of ecological organization. Valued ecological resources such as trees, fish, birds, and mammal populations are typically selected as the focus of the assessment endpoints. In ERAs, ecological entities that are valued (based on a combination of societal and ecological concerns) and to be protected are first identified and then investigated by directly measuring appropriate ecological parameters or responses (measurement endpoints) that are related to the assessment endpoints.' Unlike human health risk assessments which focus on risk to individuals, ecological risk assessments usually address risk at the population, community, or ecosystem level of organization. The exception to this is in the case of endangered or threatened species, where individuals must be protected in order to preserve the population.

4.2.5.2 Population Versus Individual/Community/ Ecosystem Endpoints

The toxicity of contaminants to individual organisms (receptors) can have consequences at the population, community, and ecosystem level. Population level effects may determine the nature of changes in community structure and function, such as reduction in species diversity, simplification of food webs, and shifts in competitive advantages among species sharing a limited resource. Ecosystem functions may also be affected by contaminants, which can cause changes in productivity, or disruption of key processes (alteration of litter degradation rate). Potential endpoints for ERAs at the individual, population, community, and ecosystem level include the following (EPA 1989c):

. Level 1: Individual Endpoints:

- Changes in behavior
- Decreased growth
- Death

- Level 2: Population Endpoints:
  - Increased mortality rate
  - Decreased growth rate
  - Decreased fecundity
  - Undesirable change in age/size class structure
- Level 3: Community Endpoints
  - Decreased species diversity
  - Decreased food web diversity
  - Decreased productivity
  - Change to less desirable community
- Level 4: Ecosystem Endpoints
  - Decreased diversity of communities
  - Altered nutrient cycling
  - Decreased resilience
  - Altered productive capability

Population-level assessment endpoints are generally recognized in ERAs because: (1) responses at lower levels (i.e., organismal and suborganismal) may be perceived as

[7] For a site where there are storage yard drums leaking to a nearby stream in which there are fish upon which bald eagles (a Federally protected species) are feeding, a likely assessment endpoint would be: impairment of reproductive success in the bald eagle. The corresponding measurement endpoint could be dose-response data for the COEC in a related species (e.g., another member of the order Falconiformes or family Accipitridae). Exposure characterization could require fish and abiotic media sampling to confirm the contaminant transport pathway and modeling of fish tissue concentrations to bald eagle tissue concentrations. Comparison of dietary (fish) eagle concentrations and modeled eagle tissue concentrations to concentrations known to impair reproduction in the eagle generates the risk estimate.

having less social or biological significance (actions may be taken to protect individuals of endangered species but only because it is prudent in light of the precarious state of the population); (2) populations of many organisms have economic, recreational, aesthetic, and biological significance that is easily appreciated by the public; and (3) population responses are well-defined and more predictable with available data and methods than are community and ecosystem responses (EPA 1989a). Populations are biologically relevant because of their role in maintaining biological diversity, ecological integrity, and productivity in ecosystems: individuals are important only in maintaining populations. Because the environmental values to be protected are sustainability of species or characteristics at higher levels of ecological organization (e.g., biological diversity), the individual level is not appropriate for assessment endpoints evaluation, except where loss of one individual could impact the survival of a threatened or endangered population.

Ecosystem responses are characterized by many of the same measures as communities: species composition and diversity, nutrient and energy flows and rates of production, consumption, and decomposition. Unlike community measures, ecosystem structure and function include nonliving stores of materials and energy along with animals, plants, and microbes that make up the biotic portion of the environment.

There is a general consensus among ecologists that results of community and ecosystem studies are complex and highly variable and, therefore, difficult to interpret. One reason for this difficulty is that contaminants exert their effects on communities both directly and indirectly. Direct and indirect toxicity can cause changes in community structure due to differences in sensitivity among species. Indirect effects such as resultant shifts in diversity, productivity, or predator-prey interactions (as the outcome of competition) are extremely difficult to predict or measure.

Indirect effects of chemicals are often cited as justification for testing at higher level of organization (Tiers III and IV). Implementation of such testing, however, tends to be expensive, time-consuming, presents great uncertainty, and may have limited relevance to the risk management decisions. If ecological endpoints are not appropriate and compelling, they will not contribute to decisions regarding site remediation (EPA 1989a).

4.2.5.3 Measurement Endpoints

When assessment endpoints cannot be measured directly, measurement endpoints are selected. Measurement endpoints are those used to approximate, represent, or lead to the assessment endpoint (EPA 1989c). Measurement endpoints should be selected so as to provide insights related to the specific assessment endpoint. In Tier I, reference toxicity values (e.g., LD_{50}, LOAEL, NOAEL) obtained from the scientific literature are used as toxicological endpoints (or surrogate measurement endpoints) for the purpose of risk characterization. Where estimated exposure concentrations far exceed the effects levels, and adverse effects are considered likely, additional confirmatory data may be needed in the decision-making process. For wildlife, confirmatory data may be obtained on a variety of measurement endpoints including chemical analyses of tissue samples from potentially exposed wildlife or their prey, or from observed incidence of disease, reproductive failure, or death (Tier II activities). Several factors should be examined in the selection of measurement endpoints, including: the sensitivity of the receptor; size comparability: diet composition and quantity; home range size; abundance; resident versus migratory species; and whether toxicity data are available (Hull and Suter 1993). Use of field measurement endpoints may also require comparison to a reference area. Where biological data are to be collected (a Tier II, III, or IV effort), the DQO process and guidance provided in the HTBW Tech***nical Project Planning*** document (USACE 1995b) should be followed.

4.2.6 Ecological Conceptual Site Model

The ECSM is a representation, often pictorial, of certain portions of the exposure characterization (CS 3). The ECSM traces the contaminant pathways through both abiotic components of the environment and biotic, food web components of the system (see CS 9). The ECSM, which may have been established in the PA/SI or RFA project phase, presents all potential exposure pathways (sources and release mechanisms, transport media, exposure points, exposure routes and receptors) and identifies those pathways which are complete (significant or insignificant) and incomplete. The ECSM helps the project team focus the data collection effort to evaluate significant pathways and address PDs requirements. At this time, data concerning potential existence and locations of

sensitive environments, endangered species, or valued resources should already have been collected.

The ECSM establishes the complete exposure pathways that are to be evaluated in the ERA and the relationship between the measurement and assessment endpoints. The ECSM forms the basic decision tool for evaluating the appropriateness and usefulness of the selected measurement endpoints in evaluating the assessment endpoints. The ECSM is also used as a tool for identifying sources of uncertainty in the exposure characterization (exposure point chemical concentrations).

Initial formulation of the ECSM in the screening ERA is based upon existing information and assumptions regarding chemical presence and migration, which now should be verified and refined with data collected during the Tier I site investigation. Exhibit 9 discusses the components of the ECSM and identifies some specific factors that should be re-examined as part of the exposure characterization (also see CS 10). Exhibit 10 discusses the role of chemical and physical properties in developing an ECSM.

The ECSM is refined in greater detail throughout the Exposure Characterization portion of the ERA. The risk assessor and project team members should review site data and information collected in earlier project efforts (PA/SI or RFA) to establish or refine the ECSM (based on more complete background information or nonchemical data) and assess potential early/immediate response actions, as appropriate. All existing data should be reviewed for quality, useability, and uncertainty before defining new data acquisition requirements. The information should be able to assist the risk assessor in developing a more definitive ECSM, or multiple ECSMs if there are multiple OUs, SWMUs, AOCs, or CAMUs/TUs (if appropriate). This information should include:

- COECs (information concerning the source characteristics, medium contamination, and background chemicals, including those of anthropogenic origin, is needed to identify COECs).
- Potential target media (groundwater, surface water, soil/sediment, and air).
- Media parameters and characteristics.
- Potential receptors in the target media.
- Major exposure routes or pathways of concern (e.g., direct contact resulting in soil or sediment ingestion or dermal absorption of contaminants in the media, consumption of food chain crops or prey species, surface water ingestion, and inhalation of contaminants in ambient air).
- Migration and transport potential of site chemicals from the source, including the effect of existing institutional controls or interim corrective measures or removal actions (e.g., groundwater capture well systems to prevent migration to surface water).
- Exposure areas or units with common COECs which also pose common exposure pathways and threats to ecological receptors.
- Potential secondary, tertiary, and quatemary sources of contaminants, and their release/transport mechanisms.
- Level of contamination when compared to available ARARs or benchmark values, and relevancy of sample location/matrix.
- Removal actions or interim corrective measures taken.
- Data useability based on quality assurance characteristics, parameter analyzed, validation results, and the way the data were compiled that may severely restrict their use in the risk assessment.

4.3 Analysis Phase - Exposure Characterization

This section discusses the development of the exposure characterization portion of a Tier I ERA. The purpose of the exposure characterization is to estimate the nature, extent, and magnitude of potential exposure of receptors to COECs that are present at or migrating from a site, considering both current and plausible future use of the site. Several components of the exposure characterization have previously been evaluated during earlier stages of the SI and ERA for the purposes of developing the ECSM and focusing investigative activities. These components include identification of COECs, key receptors and food webs, exposure media, and preliminary exposure pathways and areas. These preliminary characterizations were based upon early and often incomplete information that now must be clarified in light of the information obtained during site investigative activities.

The steps required to perform an exposure characterization are:

- Refinement of the preliminary chemical fate and transport model developed during the PA/SI and the preliminary ECSM.
- Characterization of the exposure setting.
- Identification of potential exposure pathways and intake routes.
- Quantitation of exposure.
- Assessment of exposure uncertainties.

Each of the above components is discussed in detail in following sections.

4.3.1 Exposure Setting Characterization

The objective of describing the exposure setting is to identify the site physical features that may influence exposure for both current and future scenarios. While each site will differ in the factors that require consideration, some of the more common factors are listed below and discussed briefly. Examples of how the factors may influence exposure also are provided.

- Geology. The land type and forms may influence exposure in various ways. For example, the topography of the area can influence the direction and rate of movement of chemicals to offsite areas.
- Hydrology. The possible connection of surface water bodies with groundwater should be evaluated where there are surface waters or wetlands. The potential presence of groundwater seeps should also be evaluated. The presence and character of surface water bodies or wetlands may affect potential exposures of aquatic ecosystems.
- Climate. The temperature and precipitation profiles of the area limit the types of receptors present, feeding habits, frequency of exposure (e.g., frozen surface water bodies) as well as influence the extent of chemical migration (e.g., surface water runoff and erosion, infiltration).
- Meteorology. Wind speed and direction influence the entrainment of soil particles and the extent of transport and dilution of air contaminants.
- Vegetation. The nature and extent of vegetation influence the fauna that are present and their potential for exposure through the food chain.
- Soil Type. The type of soil (e.g., grain size, organic carbon, clay content) influences soil entrainment, the degree of chemical binding, leaching potential, bioavailability, and the potential for unique vegetation types to be present. Soil characteristics also influence erosion and the resultant vegetative communities.
- Land Use. The types of receptors likely to have contact with site media and COECs depend, in part, on current and planned future land use. The appropriate current and future land uses should be identified, as is discussed above (see Exhibit 11).

Description of the site setting in the exposure characterization should involve obtaining more specific, in-depth information than was obtained during the preliminary ECSM development. The description should be supplemented by data collected during the site investigation. Description of portions of the exposure setting may have been discussed in other portions of the site report, and need only be referenced in this section. However, characteristics of the exposure setting that are specific to potential exposures should be presented.

4.3.2 Exposure Analysis

Exposure analysis combines the spatial and temporal distributions of the ecological receptors with those of the COECs to evaluate exposure. The exposure analyses focus on the chemical amounts that are bioavailable and the means by which the ecological receptors are exposed. The focus of the analyses depends on the ecological receptors being evaluated and the assessment and measurement endpoints.

4.3.2.1 Exposure Pathways identification

An exposure pathway is the physical course a chemical takes from the source to the exposed receptor (EPA 1989f).

A complete exposure pathway typically consists of the following four elements:

(1) A source and mechanism of chemical release.

(2) A transport medium such as water, soil, or forage (if the exposure point differs from the source).

(3) An exposure point or area where receptors may contact the chemicals.

(4) An exposure (intake) route through which chemical uptake by the receptor occurs (e.g., direct contact, ingestion, inhalation, or dermal absorption).

When all four elements are present, the exposure pathway is considered complete. If one or more of the components are missing (with the possible exception of the second element, transport medium), the exposure pathway is incomplete and there is no exposure and therefore no risk. It should be noted that the exposure point may be at the source itself, or the exposure point may be some distance from the source due to movement of the chemicals through the release and transport mechanisms. Circumstances should also be acknowledged where currently incomplete exposure pathways may present some future risk.'

Exposure pathways should be identified for both current land use and potential future land use, which may or may not be the same. The following factors should be considered when identifying exposure pathways for current and future scenarios:

- **What is the current and future land use?** Land use at and surrounding the site is used to identify the way in which the site is used and the types of exposure pathways that are appropriate. Risk managers and decision makers should be included at this point so that future scenario assessments only include "real world" scenarios and thereby minimize wasted assessment efforts.

- **What is the exposure area?** If relevant, specific portions of the site or offsite areas that may be contacted by potential receptors should be identified. These may be source areas or secondary and tertiary media impacted by the source areas. The plausibility of the entire site being contacted or posing a potential exposure hazard should be examined.

- **In which media are COECs presently contained?** If COECs are not present in a medium sampled during the site investigation, and are not anticipated to be in that medium during the plausible exposure period for current or future receptors, exposure to the medium does not need to be assessed.

- **Into which media are the COECs anticipated to enter within the exposure period for current and future exposure scenarios (for example, accumulation of chemicals into animal and plant species over time)?** Is predictive modeling needed?

- **For what period of time are the COECs expected to remain in the medium?** By examining the chemical's likely fate, it should be determined whether depletion or reduction of the chemical concentration needs to be considered, and whether the exposure pathway is self-limiting.

- **What types of contact with the impacted media are possible?** This determination is based upon uses of the medium and types of contact made with the medium. In general, direct contact (aquatic systems), direct uptake (plants), ingestion (animals), inhalation (animals), and dermal contact (animals) are the possible types of exposure/intake pathways assessed. Inhalation and dermal contact, however, are typically not assessed in terrestrial ERAs as these routes are not well-studied for wildlife. Most wildlife also have protective features such as fur or feathers which result in dermal contact being a negligible exposure pathway for the most part.

Exhibit 12 identifies a generic list of potential exposure pathways and mutes. A brief discussion on pertinent factors for generic exposure routes is presented below. When performing the exposure characterization, these potential exposure routes should each be examined and a decision made regarding the exposure route and pathway completeness of each for the site. Consideration of exposure routes and pathways for aquatic, versus terrestrial receptors requires somewhat different perspectives. Methods for quantifying exposure for these receptors are also

[8] Examples of this include: (1) a contaminated groundwater plume moving toward, but not yet at, discharge points to surface water bodies: (2) sediment contamination buried below the active zone of contamination that may become exposed at some future date due to natural (e.g., hurricane) or anthropogenic causes (e.g., dredging, elimination, or diversion of particulate inputs).

quite different. The approaches for assessing exposure in aquatic and terrestrial receptors are thus presented separately in the following text.

4.3.2.2 Exposure Routes for Aquatic Receptors

As discussed in the preceding section, a complete exposure pathway typically consists of four elements -- a source and release of COECs, a transport medium, an exposure point with receptors, and an exposure (uptake) route. In the aquatic habitat (fresh water, estuarine, or marine), organisms exposed to COECs am principally the aquatic organisms (e.g., algae, plants, invertebrates, fish, marine mammals) or their terrestrial consumers and predators (e.g., shore birds, waterfowl, piscivores). Exposure of terrestrial receptors is discussed in Section 4.3.2.4.

Some common exposure pathways for aquatic receptors are illustrated in CS 3 (aquatic ECSM). The aquatic ECSM serves a very useful purpose -- it enables the risk assessor to visualize where and how COECs may be moving from the source to the ultimate receptors of concern, through the various release mechanisms, secondary sources, uptake mechanisms, and primary receptors. The aquatic ECSM also shows which pathways may be significant and what measurement endpoints should be considered.

From the primary source of COECs, chemicals move toward the exposure points via the actions of direct discharge, leaching, infiltration, and erosion. Leaching and infiltration to groundwater is the most common contaminant route to aquatic receptors since many chemical releases are from tanks, pipelines, or other spills to site soils and from there to groundwater. Groundwater itself is only rarely an exposure medium for aquatic receptors, but it is a primary pathway to surface water, where chemical concentrations are rapidly diluted, and to sediment. Volatilization of organic COECs and dust generation from the primary source can occasionally be release mechanisms through the air to water and sediment, but the air pathway is rarely quantifiable except in cases of emissions from stacks or cooling towers.

Once in surface waters, chemicals are affected by a wide variety of physical and chemical processes that can change their chemical configuration, physical location, bioavailability, and toxicity within the aquatic environment. Chemicals can be lost from the water through volatilization. Chemicals in water can move into the bottom or suspended sediments via sorption or complexation with sediments or through precipitation and settling, which can be caused by an increase in the pH of the water. As indicated in the aquatic ECSM, chemicals move between water and sediment, with the sediments often serving as a source of chemicals that have been sequestered from past releases of COECs. Sediments are critical factors in aquatic ERAs because many COECs accumulate to elevated concentrations in sediments, and therefore act as sources of chemicals to the interstitial (i.e., pore) water and overlying surface waters.

Aquatic receptors are, by definition, in continuous contact with the water. They are also in contact with sediments, either bed sediments covering the bottoms of the lakes, streams, and estuaries or suspended sediments that are in the water column. Aquatic receptors can be exposed to sediments through incidental ingestion while feeding or through contact of sediment with permeable membranes. The extent of exposure to chemicals in sediment varies with several factors, including bioavailability of COECs, sediment type, sediment and water movements, organism life stage and location in the water column, migratory movements, and feeding strategies.

Aquatic receptors can also be exposed to COECs by ingesting prey organisms that have bioaccumulated chemicals, typically organic compounds such as pesticides or PCBs. Evaluation of the potential for risk through exposure of aquatic receptors to COECs is increasingly complex for the three exposure media -- water, sediment, and prey. Because of this increasing level of complexity in assessing the potential for exposure and risk, water is the exposure medium often evaluated first, by screening against established water quality criteria and standards or laboratory bioassay results (see Chapter 5). Sediment contaminant concentrations can be compared to sediment standards, guidelines, or COEC sediment levels that are back-calculated from water criteria using chemical-specific K_p values in an equilibrium partitioning approach. Finally, potential risk from ingesting contaminated prey can be evaluated by using food ingestion models that consider all three pathways.

4.3.2.3 Exposure Route Modifying Factors for Aquatic Receptors

Numerous factors modify the extent of exposure to COECs in the aquatic environment. Although factors generally fit into physical, chemical, and biological categories, the factors act in combination with each other to affect the exposure of aquatic receptors to COECs, bioavailability of the COECs, and the toxicity of the COECs.

4.3.2.3.1 Physical Factors. Physical factors affect the release mechanisms that move COECs from the source

along a transport medium to the exposure point; physical factors also can influence the movements of receptors and their presence at the COEC exposure point. Referring to the aquatic ECSM in CS 3, these physical factors include discharge, leaching, infiltration, erosion, dilution, settling, and resuspension on the physical media.

An example can serve to illustrate the physical factors that influence the presence and concentration of COECs at the exposure point. COECs in contaminated soils can move into groundwater through leaching from contaminated soils. Groundwater then moves toward surface waters at a given rate that, when multiplied by a COEC concentration in groundwater, results in a loading rate to the surface water. Groundwater typically moves through the interstices of the sediment where the COECs can accumulate in the sediment or can be diluted when mixed with the surface water. Grain size and shape of the sediment particles affect the tendency of COECs to adsorb onto the sediment, thereby reducing their mobility in the aquatic environment. Throughout the pathway, chemical factors such as pH, oxidation-reduction potential (Eh), and presence of other chemicals interact with the physical factors described and affect the presence, concentration, and form of the COECs at the exposure points (sediment and surface water).

Physical factors can also influence the movement and location of aquatic receptors, thus affecting their exposure to COECs. In an interactive scenario analogous to that described above for physical and chemical factors, physical factors interact with biological factors that also affect exposure of the receptors. Physical factors such as current velocities, water temperature, and water salinity can influence seasonal migratory movements and rates of growth that, in turn, can influence the location of the receptors relative to COEC concentrations.

4.3.2.3.2 Chemical Factors. Chemical factors can affect the chemical and physical form of the COECs, their bioavailability, and ultimately, their toxicity to receptors. In fresh water, pH, Eh, hardness, and the presence of dissolved and particulate organics affect the form and availability of many metals. The overall effect of these confounding natural factors on toxicity of metals is reflected in the water effect ratio (WER), which is based on the relative toxicities of a COEC when tested in a dilution series using laboratory water versus the same COEC tested using upstream natural water as dilution water.

In sediments, some of the same chemical factors influencing exposure of receptors to COECs in water also affect exposure to COECs in sediments. Two other chemical factors, total organic carbon (TOC) and acid volatile sulfide (AVS), strongly affect exposure of receptors to COECs in sediments. Increased levels of organic carbon in sediments tend to bind nonpolar organics to the sediment. This effect is reflected in the chemical-specific organic carbon-water partition coefficient, K_{oc}.

AVS affects the binding of metals to sediments by providing additional binding locations for metals. The metals primarily affected include cadmium, copper, lead, nickel, and zinc. These metals replace iron in iron sulfide complexes. If the concentration of AVS exceeds the combined concentration of these five metals as determined through a simultaneous extraction procedure referred to as SEM (i.e., SEM/AVS ratio is greater than l.0), the mobility of the metals is decreased due to the abundance of binding locations. If the AVS level is lower than the SEM level (i.e., SEM/AVS < 1.0) there may be a lack of binding locations, and the five SEM metals are more available (and potentially toxic) to receptors. The results of the AVS and SEM analyses should be interpreted on a weight-of-evidence basis because of the confounding influence of other chemical and physical factors.

4.3.2.3.3 Biological Factors. Several biological factors affect the co-occurrence and exposure of aquatic receptors to COECs in the water and sediment exposure media. Similar factors also affect the exposure of prey organisms to COECs that can bioaccumulate in the prey tissues, thus contributing to the overall exposure of receptors to bioaccumulative COECs.

Some of the more important biological factors affecting exposure to COECs are life stage, feeding strategy, and migratory movements of the receptors. In a typical exposure scenario, COECs are found in sediments and water but are at higher concentrations in the sediments. Several benthic invertebrate species (e.g., oysters) have larval stages that are planktonic and adult life stages that are sessile (i.e., attached to a substrate). If that substrate or the surrounding sediment has elevated COEC concentrations, the adult is likely to be exposed to COECs, whereas the larval stage is less likely to be exposed since it is not directly associated with the sediment.

Feeding strategy can also directly influence exposure to COECs. If a receptor feeds in or along the sediment and COECs are at elevated levels in the sediment, the receptor is apt to be exposed to COECs through ingestion of prey organisms that have accumulated COECs and incidental ingestion of sediment. If a receptor feeds higher in the water column, it is less likely to be exposed to COECs in

sediments and sediment-related prey. If a receptor is an upper-level predator (e.g., black drum), it is apt to be exposed to bioaccumulative COECs through ingestion of primary or secondary consumers that have elevated levels of COECs in their tissues. In contrast, a primary consumer that eats plant material is less apt to be exposed to COECs since chemicals are not apt to be accumulated to elevated levels in the vegetation.

Migratory movements of receptors can directly affect exposure to COECs. The effect of migratory movements is readily illustrated through a comparison of a fish that follows anadromous migratory patterns (i.e.. moves from the ocean through an estuary into fresh water to spawn and then returns to the ocean) to a resident species of the estuary. If the estuary and its sediments have elevated levels of COECs, the resident species is exposed throughout its life, while the anadromous species is only briefly exposed. In the case of the migratory species, although its year-round exposure cannot be confirmed, it often is assumed that the species is exposed to the COECs only while it is in the vicinity of the contaminated sediment or other exposure medium.

The manner in which several of these biological factors may affect the exposure characteristics of receptors to COECs provides an emphasis for going beyond mere listing of species present which are formulated during the initial site description and/or reconnaissance. A functional evaluation of how the species present actually use the habitat is necessary. Uses such as spawning grounds, nursery grounds, or adult food foraging should be distinguished so that significant biological factors influencing exposure may be integrated in any evaluation of exposure routes.

4.3.2.4 Exposure Routes for Terrestrial Receptors

Typical exposure pathways and routes for terrestrial (and wetland) receptors are illustrated in CS 3. Similar to the aquatic ECSM, the terrestrial ECSM enables the risk assessor to visualize where and how COECs may be moving from the source to the ultimate receptors of concern, through the various release mechanisms, secondary sources, uptake mechanisms, and primary receptors. The three principal potential exposure routes for terrestrial (animal) receptors are: dermal absorption, inhalation, and ingestion. Exposure route for plants include both root uptake and foliar absorption.

4.3.2.4.1 Dermal Contact with Soil, Sediment, Water, and Air. Dermal contact with soil, sediment, or water is a potentially significant exposure route for soil-dependent terrestrial animals (e.g., invertebrates and microbes) or animals which spend considerable time submerged in surface water (e.g., muskrat, beaver). Wildlife may receive indirect dermal exposure by brushing against surfacecontaminated vegetation. However, dermal absorption is generally an insignificant intake route for terrestrial wildlife, as such receptors are largely protected by their fur, feathers, or scales. Soils that are covered by pavement are unlikely or impossible to contact. and the assessment should account for this accordingly. Further discussion of the dermal exposure route is presented in Section 4.4.5.3.

4.3.2.4.2 Inhalation Exposure to Air. Inhalation exposure by terrestrial receptors could occur to both vapor phase chemicals and particle phase chemicals. Quantitative methodologies for evaluating this exposure route in terrestrial fauna are not well-established, but have been developed in order to evaluate wildlife exposure to herbicide sprays (USDOI 1991). Consideration should be given to the chemical form applied, degree of chemical absorption, methods for estimating exposure point concentrations, and toxicity values where there is the potential for this to be a significant pathway. Further discussion of the inhalation exposure route is presented in Section 4.4.5.2.

4.3.2.4.3 Ingestion of Water. Ingestion of water by terrestrial wildlife should be examined where there is a significant water source. Analysis of unfiltered surface water samples best represents chemical concentrations to which a terrestrial receptor may be exposed. Potential exposure of biota to chemicals in small, temporal, surface water puddles is typically not evaluated (unless concentrations are extremely toxic) as the exposure is likely to be insignificant compared to exposure from other pathways.

4.3.2.4.4 Ingestion of Soil or Sediments. Ingestion of soil or sediment should be considered for all exposure scenarios that provide direct access to soil. Many wildlife species ingest soil while feeding, but ingestion rates are known for only a few species. Soil ingestion rates have been measured for certain livestock in order to estimate pathways for human exposure (EPA 1990d). Similar estimates of soil ingestion rates for grazing wildlife may also be used.

Except for earthworms and some other soil invertebrates, most terrestrial animals do not “eat” dirt, but ingest only a limited amount of soil incidental to feeding (typically less than 10 percent of food intake). Deliberate ingestion of soil may occur under some circumstances, such as for

sodium (salt licks) or calcium content, or for grit. Soil intake may also be a result of incidental (direct) ingestion from soil adhered to the surface of food/prey items or from grazing, preening/cleaning, or burrowing activities. Under certain site conditions, the soil in the gut of earthworms may be an important exposure medium for animals that eat these organisms (Beyer et al. 1993). The sandpiper group is generally thought to have the highest rate of soil/sediment ingestion (7 to 30 percent) due to their diet of mud-dwelling organisms. Relatively high rates are also reported for wood ducks (11 percent), raccoon (9.4 percent), and woodcock (10.4 percent), which feeds extensively on earthworms, and Canada goose (8.2 percent) (Beyer, Connor, and Gerould 1994). Soil ingestion rates for small rodents are reported at less than 2 percent (Beyer, Connor, and Gerould 1994).

4.3.2.4.5 Ingestion from Diet. Exposure of high trophic level receptors to lower trophic level plant or animal species into which chemicals have accumulated should be considered in cases where COECs have the potential to biomagnify. Organic chemicals with high log KOW (>3.0, EPA 1994f) or high molecular weights (i.e., pesticides and PCBs) are more likely to be transferred through the food web than those with low molecular weights. Plants can take up chemicals with low log K,, values by way of their roots, but cannot transport significant amounts of chemicals with high molecular weights and high low K_{ow} values in the same manner (EPA 1989c). Such chemicals can, however, be transported via the air pathway and deposited and adsorbed to plant surfaces (leaves, etc.). Predator species at the top of the food web are the most vulnerable to chemicals that biomagnify. In general, long-lived and larger species (that accumulate fat) have a greater opportunity to accumulate these compounds as well. Also, higher trophic level species, particularly bird species, may be more sensitive to the COECs than the animals on which the birds prey. For terrestrial species, BCFs as little as 0.03 can be significant if the residue is toxic (EPA 1989a).

4.3.2.4.6 Plant Uptake. The soil-plant system is an open system subject to inputs, contaminants and fertilizers, and to losses, through plant consumption, leaching, erosion, and volatilization (Alloway 1990). Factors affecting the contaminant amounts absorbed by a plant are those controlling: (1) concentration and speciation of the contaminant in the soil solution, (2) movement of the contaminant from the bulk soil to the root surface, (3) transport of the contaminant from the root surface into the root, and (4) translocation from the root to the shoot (Alloway 1990). Plant uptake is dependent on both the total quantity of the contaminant in soil as well as the root mass present. Terrestrial plant uptake of contaminated water can be a potentially significant pathway if the plant is a wetland species or a phreatophyte (plants that depend on groundwater for their moisture). The uptake route for water is generally insignificant for xerophytic and mesophytic plants which have more shallow root systems and depend on surface water from rainfall.

In addition to the root absorption, plants can absorb contaminants through their foliage. Foliar absorption of contaminants (in the form of solutes) depends on the plant species, its nutritional status, the thickness of its cuticle, the age of the leaf, the presence of stomata guard cells, the humidity at the leaf surface, and the nature of the solutes (Alloway 1990). The uptake route from air to terrestrial plants can be a potentially significant pathway for vapor phase and particulate phase COECs. While chemical concentrations found in the air pathway generally pose only a minimal risk to animal species, lichens, in particular, and trees can be especially sensitive to airborne contamination. In ERAs conducted near forested areas, air may be an important environmental transport medium for certain plant groups.

4.3.2.5 Exposure Route Modifying Factors for Terrestrial Receptors

Numerous factors influence the spatial distribution and abundance of a population of animals relative to the spatial extent of contamination. Exposure modifying factors such as home range, mobility, and life-cycle attributes (breeding seasons, longevity) should be evaluated in the exposure characterization. Normalizing factors (e.g., body weight, growth rate) for the various receptors am also to be considered during exposure quantitation.

4.3.2.5.1 Area Use. Home ranges and feeding territories should be considered as they may greatly influence potential exposure. The size and spatial attributes of a home range often are determined by foraging activities, but also might depend on the location of specific resources such as dens or nest sites. Home ranges depend on habitat quality (e.g., carrying capacity), with home range sizes generally increasing as habitat quality decreases to a condition beyond which the habitat does not sustain even sparse populations. Home ranges can also vary by sex, season, and life stage. Population density (the number of organisms per unit area) also influences potential exposure.

The mobility of a receptor is usually expressed in terms of the average foraging range of the key receptor (or similar species) under consideration. Mobile receptors

typically include the larger vertebrates and grazing species (deer, elk, antelope), predators (fox, coyote), migratory birds (robin), and predatory birds (hawk, eagle, falcon). The foraging areas of these transitory species are likely to be several square miles. Smaller mammals and birds constitute a category of mobile receptors whose foraging areas range from a fraction of an acre to several acres. Plants, soil organisms, and most flightless invertebrates can be considered to be stationary due to the small area within which they live their lives. In each case, to quantify chemical intake for the key receptor, an area use factor should be applied to account for the foraging range of the key receptor, as compared to the areal extent of the contaminated area. The area use factor is defined as the ratio of home range, or feeding/foraging range, to the area of contamination or the site area under investigation.

4.3.2.5.2 Exposure Frequency. Exposure frequency is another type of modifying factor that can be used to adjust exposure and chemical intake for a key receptor. Resident species, rather than migratory species, should be evaluated first (when they are present), due to the longer exposure duration potential of the resident species. Migratory species should be evaluated where there is the potential for acute toxic effects from infrequent exposure or where exposure pathways present a greater exposure potential. Magnitude and frequency of exposure should be taken into consideration where the assessment endpoint and toxic effect are based on chronic exposure duration in the test organism.

4.3.2.5.3 Seasonal Activity Patterns. Many seasonal or life-cycle attributes affect an animal's activity and foraging patterns in time and space and their exposure potential. For example, many species of mammals, reptiles, and amphibians hibernate or spend a dormant period in a burrow or den during the winter months. Longevity and mortality rates also influence exposure potential and are important in determining potential for chronic exposures.

Seasonal variability may also affect the interpretation of ecological data and should be considered in the design of any sampling plan. Data obtained during any short period could be accurate, but only for that period. For example, pinyon mice apparently suffer substantial winter mortality (Morrison 1988). Trapping only in fall or spring would falsely indicate a relatively high or low population size, respectively. A full year of sampling is generally required to adequately characterize an ecological population. Some vertebrate population cycles, however, can take much longer: e.g., a 23-fold difference between peaks and low numbers in snowshoe hares was described in one 15year study (Keith 1983). and it took 12 years for a relationship between conifer seed crop and red squirrel abundance to be repeated (Halvorson 1984).

4.3.2.5.4 Dietary Composition. Dietary composition varies seasonally and by age, size, reproductive status, and habitat. Dietary composition is an important consideration for higher trophic level organisms indirectly exposed to chemicals that bioaccumulate or biomagnify.

4.3.2.5.5 Habitat Preferences. Many wildlife species have habitat preferences that may increase or decrease their potential exposure to contaminants. Woodcocks, for example, will remain longer feeding in fields with tall cover than in those with short vegetation (Hull and Suter 1993). Robins, on the other hand, prefer fields or lawns maintained by regular mowing.

4.3.2.5.6 Foraging Style. Animals with different foraging styles may also have different morphologies and activity patterns that ultimately influence exposure to contaminants. Piscivorous avian species, for example, can be classified into three general types of foraging styles: raptorial predators (bald eagle), diving and swimming predators (common merganser), and wading predators (great-blue heron).

4.3.3 Exposure Profiles

Using information obtained from the exposure analysis, the exposure profile quantifies the magnitude and spatial and temporal patterns of exposure. The exposure profiles developed for the ecological receptors and COECs serve as input to the risk characterization.

4.3.3.1 Quantitation of Exposure

For soil-dependent organisms (plants, soil invertebrates, soil microbes), soil exposure concentrations are directly evaluated against soil criteria, similar to AWQC for aquatic organisms. Standard soil criteria like the AWQC are not currently available, but are under development by EPA. ORNL (1994) has recently published toxicological benchmarks for terrestrial plants and soil/litter invertebrates.

For wildlife, chemical intakes am estimated for exposures occurring from complete exposure pathways for each receptor group. The exposures are quantified with respect to the magnitude, frequency, and duration of exposure to derive an estimate of chemical intake.

Chemical intake by wildlife is estimated by combining two general components: the chemical concentration

component and the intake/exposure factors component. In the following subsections the estimation of the exposure point concentrations, discussion of the selection of intake and exposure factors, and the specific methods of combining them mathematically are presented.

4.3.3.2 Determining Exposure Concentrations (Aquatic and Terrestrial Scenarios

Exposure concentrations represent the chemical concentrations in environmental media that the receptor will contact. Exposure concentrations may be derived from either data obtained from sampling or from a combination of sample data and fate and transport modeling, both of which are described below.

For current (and perhaps some future) exposure scenarios where current site data are anticipated to be reasonably reflective of exposure concentrations over the exposure period, the exposure point concentration can be directly derived from site data. For future (and perhaps some current) exposure scenarios, where current site conditions are not anticipated to be reasonably reflective of exposure concentrations over the exposure period, some form of fate and transport modeling or degradation calculations can be applied. However, these too will be based upon current site conditions as a starting point. The available data need to be examined critically to select the most appropriate data in each medium to describe potential exposure. These data sets can vary depending on the receptor-specific exposure factors. For example, soil data for soil-dependent organisms (earthworms) and burrowing mammals would include samples from greater depths than direct soil exposure for large herbivores. General factors to consider when deriving exposure concentrations are identified in Exhibit 13.

Since the exposure point concentration used in the assessment is a value that represents the most likely concentration to which receptors may be exposed, a value that reflects the central tendency of the data is appropriate to use. In order to account for uncertainties in the ability of the measured data to reflect actual site conditions, the concentration relating to the 95% UCL of the arithmetic mean is usually used as the exposure point concentration. In cases where the 95% UCL concentration exceeds the maximum detected value (which can occur in small data sets or data sets with a large variance), the maximum value is used[9] (see CS 11). It is worth noting that use of the central tendency value may not adequately address chemicals that are highly bioaccumulative or biomagnify.

EPA has recommended that the approach presented in Gilbert (1987) be used to calculate the exposure point concentration term (EPA 1992h). This approach derives the 95% UCL of the arithmetic mean, using log-transformed data. EPA recommends assuming a log-normal distribution unless an alternate distribution can be demonstrated to be appropriate. If a normal distribution is appropriate for the data the Student's t test can be applied. Exhibit 14 presents methods to calculate the 95% UCL concentration by these two distributions.

Often in data sets, a number of data points for a given chemical in a given medium will be reported as undetected or less than some quantitation limit.[10] Common errors in reporting and handling these data can occur and include: (1) omission of detection limits, (2) failure to define detection limits which am reported, and (3) unjustified treatment of nondetects as zero. In calculating the sample mean (x) and sample standard deviation(s), some method of handling these "less than" values is needed. Also, the uncertainties in statistical comparisons and variance biasing that can ensue when nondetection samples are assumed to be a single value should be addressed.

Four options for the treatment of nondetect values are discussed in Gilbert (1987):

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[9] Reasons for the 95% UCL value exceeding the maximum values are numerous. Such a circumstance may be indicative of incomplete site characterization. This circumstance may also reflect high variance due to biased, purposive sampling rather than random sampling.

[10] Analytical laboratories frequently code samples as "below detection" when the actual concentration was detectable with the method employed but fell below the Contract Laboratory Program (CLP) contract reporting limit. This situation is easy to spot because all "below detection" samples will have the same value. Sample specific (not generic) practical quantitation limits (PQLs) or method detection limits (MDLs) should also be reported.

CASE STUDY 11

CALCULATION OF EXPOSURE POINT CONCENTRATIONS (TERRESTRIAL ECOSYSTEM)

The exposure area for a small mammal is defined as the area of the former metal scrap piles. Therefore, data from locations SS-1 through SS-4 describe the exposure area and are combined to derive the exposure point concentrations. Assuming a log-normal distribution and applying the statistical approach for calculating the 95% UCL on the arithmetic mean for a log-normally distributed population (as recommended by EPA), the following exposure point concentrations are derived:

Chemical	Mean Conc	95% UCL	Max Conc
Cadmium (mg/kg)	85.6	104.3	100

Note that the 95% UCL concentration is greater than the maximum detected concentration. This occurred because the small sample size resulted in a high "H" statistic value and an artificially high 95% UCL. Since the 95% UCL exceeds the maximum detected value, the maximum value is used as the exposure point concentration. This concentration will be used as the exposure point concentrations for soil ingestion by wildlife and soil contact by soil-dependent organisms.

- Use only the quantified values
- Assume the nondetected values are equal to the quantitation limit.
- Assume the nondetected values are equal to zero.
- Assume the nondetected values are some value between zero and the quantitation limit, such as one-half of the quantitation limit.

The first three methods are biased for both the population mean (μ) and the population variance (σ^2); the fourth is unbiased for p if all measurements between zero and the quantitation limit have a uniform distribution. EPA discusses use of these approaches and recommends using one-half of the sample quantitation limit (SQL) if there is reason to believe that the chemical is present in the sample (such as being detected in other similar samples), or using the full SQL if there is reason to believe that concentrations are closer to the SQL than one-half of the SQL (EPA 1989f). The assumption of a value of zero for nondetects should be made only if site-specific information indicates that a chemical is not likely to be present in a sample. In *RAGS I*, EPA (1989f) indicates that omission of nondetected results is not appropriate. Additional discussion can be found in EPA Region III's (1991f) *Technical Guidance on Chemical Concentration Data Near the Detection Limit.*

In certain situations, an unusually high quantitation limit may be assigned to a nondetected result due to matrix interferences, high concentrations of other chemicals in the sample, presence of blank contamination, or other factors. When one-half (or all) of this quantitation limit is used to derive summary statistics, the mean concentration may exceed the maximum detected value. When the 95% UCL concentration is calculated, it, too, will be above the maximum detected value. In these situations, guidance recommends using the maximum detected value in place of the 95% UCL concentration. It should be noted, however, that if many of the undetected results have unusually high detection limits, these high limits may be masking the presence of the chemical. In this case, the utility of the data set and the need for additional analysis should be examined.

As an option, to obtain a more representative mean and UCL concentration, the sample with the unusually high quantitation limit can be removed from the calculation of the mean concentration, reducing the sample number ("n") by one. If the resultant mean concentration still exceeds the maximum detected value, the next highest quantitation limit should be removed, and the mean recalculated. This process can continue until a mean concentration less than the maximum concentration is attained. The 95% UCL concentration then can be recalculated, as well.

Sample size influences the magnitude of the statistical confidence of the mean, as demonstrated by high 95% UCL concentrations for small sample sets. The reliability coefficients (the "H" or "t" value used in calculating the UCL concentration, obtained from statistical tables) are a function of the number of samples, and increase with a decreasing number of samples. The overall effect, then, of a small sample size upon statistical confidence is to increase the UCL concentration. In data sets in which minimum requirements have been set prior to sampling, the risk assessor should ensure that an adequate number of samples have been collected to minimize this problem.

Exposure point concentrations are also sometimes derived from a combination of measured data and the application of environmental fate and transport modeling. For the most part, measured data points are preferred over modeled data: where data are modeled, some level of validation and ground-truthing is required (exceptions include ERAs for proposed incinerator emissions/deposition). Common instances in which modeling may be used to predict exposure point concentrations include:

- When the potential exposure point is at a location other than those for which monitoring data are available (e.g., in offsite areas or locations in-between those which have been described).
- When the potential exposure is anticipated to occur in the future (e.g., proposed incinerator emissions).
- When the chemical concentrations are anticipated to change with time.
- When the potential exposure is in a medium other than those sampled (e.g., exposure to air impacted by contaminated soil, when only soil was analyzed).
- When the potential exposure point concentration is anticipated to increase with time (as with bioaccumulation into animal or plant species).
- When the bioavailable portion of the chemical concentrations is anticipated to change with time (e.g., seasonal AVS fluctuations, fluctuations

between fresh and saline water either with migration downstream or tidal influence).

Many fate and transport models are available with which to predict exposure point concentrations from existing site data. These models are presented in other references, including the following:

- *Superfund Exposure Assessment Manual* (EPA/ 540/l-88/001,4/88) (EPA 1988h).
- *AirlSuperfund National Technical Guidance Study Series* (Volumes I - V) (EPA 1989h,i; 1992i, 1993d: 1995g).
- *A Workbook of Screening Techniques for Assessing Impacts of Toxic Air Pollutants* (EPA-450/4-88-009, 9/88) (EPA 1988i).
- *Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-water Models* (EPA/600/8-88/075, 5/88) (EPA 1988j).
- *Selection Criteria for Mathematical Models Used in Exposure Assessments: Surface Water Models* (EPA/600/8-87/042, 7/87) (EPA 1987a).
- *Rapid Assessment of Exposure to Particulate Emissions from Surface Contamination Sites* (EPA/600/8-85/002, 2/85) (EPA 1985).
- *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions* (EPA/600/6-90/003, 1/90) (EPA 1990d).
- *Assessment and Control of Bioconcentratable Contaminants in Surface Water* (EPA 1991e).

The type of model and level of effort to be expended in estimating exposure point concentrations with models should be commensurate with the type, amount, and quality of data available. In general, it is best to begin with a model that employs simplified assumptions (i.e., a "screening level" approach) and determine whether unacceptable ecological risks are posed by the exposure point concentration estimated by this approach. If so, a more complex model that applies less conservative assumptions can be used.

The validity of the estimation provided by the model will strongly depend on the variables that are input to the models. Efforts should be taken to ensure the use of input variables that best reflect site conditions and that are not overly conservative.

Initial abiotic sampling designs are often not established with sampling for the selected key ecological receptors in mind. Often, biased sampling designs are selected in order to best characterize potential hot-spot conditions and the nature and extent of contamination. Calculation of a 95% UCL or averaging of these point concentration results tends to result in an overestimation of the exposure concentration (and risk) for larger mobile animals (deer, antelope) that don't forage onsite or at any particular spot for extended periods of time. Where the receptor's home range is greater than the contaminated area, area use and exposure frequency factors can be used to modify the areawide intake concentration. Where the receptor's home range lies within the contaminated area, alternate methods of removing the bias from the areawide exposure concentration (e.g., weighted average, Theissen polygons) data set can be used, but may result in an over- or underestimate of exposure. Probability analysis techniques (Monte Carlo) and programs (e.g., Crystal Ball@) are also gaining greater acceptance as a means to provide a more realistic estimate of actual exposure conditions by generating a distribution of probable exposure concentrations (See Appendix E).

4.3.3.3 Calculating Intake for Terrestrial Wildlife

The following discussion of terrestrial wildlife intake focuses on the oral ingestion route only. Oral intake (ingestion) of three environmental media (food, water, soils/sediment) are the principal routes evaluated in a Tier I terrestrial ERA, as they typically represent the most significant exposure pathways. Quantitative data and methodologies by which to calculate inhalation and dermal contact rates for various terrestrial wildlife (or livestock) are generally lacking: limited guidance on these intake routes are provided by EPA (1990d, 1993e) and USDOI (1991).

For each receptor, the following four exposure factors are considered in the calculation:

- Food Intake (FI) - These rates can vary by age, size, and sex and by seasonal changes in ambient temperature, activity levels, reproductive activities, and the type of diet consumed. Food ingestion rates are available in the published literature for a limited number of wildlife species. Methods for estimating food ingestion rates are provided in EPA's (1993e) *Wildlife*

Exposure Factors Handbook (see Exhibit 15). Food ingestion rates are typically expressed on a wet-weight basis. Where results from wildlife laboratory studies are expressed on a dry weight basis, this difference may be ignored as the moisture content of most laboratory studies is typically less than 10 percent water (Beyer and Stafford 1993).

- Dietary Composition (DC) - Dietary composition varies seasonally and by age, size, reproductive status, and habitat. Dietary composition is typically expressed as percentage of total intake on a wet-weight basis.

- Water Intake (WI) - Water consumption rates depend on body weight, physiological adaptations, diet, temperature, and activity levels. Some species (e.g., deer mouse) can meet most of their daily water requirement with only the water contained in their diet. Water ingestion rates can be estimated using allometric equations published by EPA (1993e; see Exhibit 15).

- Soil/Sediment Intake - Soil or sediment intake is usually expressed as a percent of dietary intake. Data quantifying soil/sediment intake are limited; values for selected wildlife species are presented in the *Wildlife Exposure Factors Handbook* (EPA 1993e). As noted earlier, soil/sediment intake rates of up to 30 percent of diet are reported for some wildlife.

4.3.3.3.1 Intake Equations. Estimating contaminant exposure for wildlife consists of summing the exposure received from each separate source. Total exposure intake for terrestrial wildlife is represented by the following generalized equation (ORNL 1994):

$$E_{total} = E_{food} + E_{water} + E_{soil}$$

where

E_{total} = exposure from all sources

E_{food} = exposure from food consumption

E_{water} = exposure from water consumption

E_{soil} = exposure through consumption of soil and sediment (incidental or deliberate)

Exposure or chemical intake by terrestrial wildlife is reported as "average daily dose" on a body weight basis, i.e., milligrams chemical per kilogram body weight per day (mg/kg-bw/d). It is fundamental that exposure, chemical intake, and toxicity benchmark determinations be adjusted to account for body weight and dietary intake of the organism, to account for the differences in food intake relative to body weight of the various organisms being compared. Exposure evaluations (and toxicity benchmark selection) based on a comparison of dietary chemical concentrations (i.e., milligrams chemical per kilogram food, mg/kg) amongst wildlife receptors (e.g., deer and rabbits) are sometimes mistakenly attempted in an ERA as a means to "simplify" the quantitation process. The following equations for chemical intake exemplify the simplified assumption models commonly used in a baseline ERA. More complex assumption models can be found in the *Wildlife Exposure Factors Handbook* (EPA 1993e).

Chemical intake is estimated by applying the following generic equation to each exposure source (e.g., food):

$$\text{Daily Intake}_{food}\ (\text{mg-chem/kg-bw/d}) = \frac{C \times FI \times EMF}{BW}$$

where

C = concentration of chemical in food (i.e., mg-chem/kg-food)

FI = food intake rate (kg-food/day)

EMF = exposure modifying factors such as area use (percent of home range that is contaminated) or exposure frequency (percent of time spent in contaminated area) that describe the magnitude and frequency of exposure (default value is 1.0) (unitless)

BW = body weight of receptor (kg)

Selection of appropriate intake and exposure modifying factors is a critical component of the assessment, for these values largely determine the overall risk estimates. The *Wildlife Exposure Factors Handbook* (EPA 1993e) presents exposure profiles for selected species of birds, mammals, and reptiles and amphibians. Each species profile provides a series of tables presenting values for normalizing (body weight) and contact (intake) rate

factors, exposure modifying factors (home range), dietary composition, population dynamics, and seasonal activity patterns. Additional information on wildlife exposure factors can be found in the published literature including ORNL's (1994) *Toxicological Benchmarks for Wildlife.* Allometric equations for estimating wildlife feeding and drinking rates are provided in Exhibit 15. Some general points that should be considered when selecting exposure factors are identified in Exhibit 16. In an ERA, all exposure and intake factors applied to the assessment should be identified in tabular form, with the source of the value identified and a rationale for the use of the value presented.

If C and FI vary over time, they may be averaged over the exposure duration (ED). However, it is not always appropriate to average intake over the entire exposure duration: For example, a given quantity of a chemical might acutely poison an animal if ingested in a single event, but if that amount is averaged over a longer period, effects might not be expected at all. Similarly, developmental effects occur only during specific period of gestation or development. C, FI, and BW should be selected so as to be comparable to the specific reference toxicity value that is used.

Wildlife can be exposed to contaminants in one or more components of their diet and different components can be contaminated at different levels. For example, the diet of the deer mouse, an omnivorous key receptor commonly assessed in ERAs, primarily consists of invertebrates and terrestrial plants. The daily intake for the deer mouse is thus expressed as [(chemical concentration in invertebrates x % ingested) + (chemical concentrations in terrestrial plants x % ingested) x daily food intake] / deer mouse body weight. To calculate daily dose for diets with more than one component, the following generic equation may be used:

Daily intake (mg-chem/kg-bw/d) =

$$\frac{[(C_1 \times FI_1)\, f_1 + (C_2 \times FI_2)\, f_2 + \ldots (C_i \times FI_i)\, f_i] \times EMF}{BW}$$

where

C_i = concentration of chemical in food (i.e., mg-chem/kg-food or ppm)

FI_i = food intake rate (kg-food/day)

f_i = fraction of food item in diet

EMF = exposure modification factors (default value is 1.0) (unitless)

BW = body weight of receptor (kg)

The same generic equation can be used to estimate daily intake of the contaminant from food, water, and soil/sediment ingestion routes. For example, to calculate the daily dose for a receptor exposed to a contaminant in diet and water, the following equation may be used:

Daily intake (mg/kg-bw/d) =

$$\frac{[(C \times FI) + (C \times WI)] \times EMF}{BW}$$

where

C = chemical concentration in food or water (i.e., mg/kg, mg/L, ppm)

FI = food intake rate (kg-food/day)

WI = water intake rate (L-water/day)

EMF = exposure modifying factors (default value is 1.0) (unitless)

BW = body weight of receptor (kg)

In order to describe a range of potential exposures presented by a site, the ERA may assess more than one potential exposure scenario. Use of a single expression of potential ecological risk does not provide information on the possible range of ecological risks, and may not allow the risk manager to evaluate the "reasonableness" of the single estimate. Current risk assessment guidance for human health suggests the strategy for determining the exposure point concentration for soils should depend on spatial contaminant distribution. If a contaminant is widely distributed throughout the site, the exposure point concentration should be based on the 95% UCL of the arithmetic average for all site samples, including non-detects. However, if the contamination is unevenly distributed, i.e., "hot-spot" areas exist, these areas should be evaluated by determining exposure concentrations in these areas. A percentage of time that the receptor spends on the site in these "hot-spot" areas should be factored into the intake equation. Use of a "hot-spot" high end as well as use of the 95th UCL exposure scenario are also applicable to ecological risk. Presentation of these and other scenarios (e.g. central tendency) provide information

about the range of potential risks to the ecological receptors.

4.3.3.3.2 Intake Variable-s. To develop a "high end" assessment, EPA recommends identifying the most sensitive parameters and using maximum or near maximum values for one or a few of these variables, leaving other variables at their mean values. Adopting maximum values for all intake and exposure parameters will virtually always result in a risk estimate that is above that experienced by the most exposed receptor and is, therefore, inappropriate. EPA human health guidance ***(RAGS I)*** recommends applying 90th or 95th percentile values for the exposure point concentration term" and exposure frequency variables, and average values for other parameters such as body weight.

The average exposure (central tendency) is derived by applying average values for all intake and exposure (e.g., area use) parameters. Although description of an average exposure is not particularly useful when exposure varies greatly across all potentially exposed populations, it can provide information on the extent of impact of the exposure parameters that were maximized in the high end exposure. Use of a median value for exposure parameters, such as a geometric mean rather than an arithmetic mean, is more meaningful since it represents a midpoint value (i.e., half the population above and half below). Specific ERA guidance is lacking regarding the use of average versus 95th UCL values for exposure frequency and intake variables, as quite often are the data to calculate such values for specific ecological receptors.

Contaminants may enter terrestrial food chains directly from soil/sediment, water, or air or indirectly through the consumption of plants (producers) or animal prey (consumers). The following sections discuss means for determining chemical concentrations in plants and prey.

4.3.3.3.3 Estimating Chemical Concentrations in Plants. The three principal mechanisms by which contaminants can bioaccumulate in plants include: uptake by roots, direct deposition on exposed plant tissues, and air-to-plant transfer of vapor-phase contaminants. The dative importance of each pathway to the wildlife consumer depends on the specific plant, the contaminant, site-specific physicochemical conditions, and the preference of the wildlife receptor for the particular plant.

The plant-soil bioaccumulation factor (BAF_{plant}) or transfer coefficient is a measure of a contaminant's ability to accumulate in plant tissue and is defined as the chemical concentration in the plant (dry weight) divided by the chemical concentration in soil (dry weight). Bioaccumulation factors may be derived differently for inorganic and organic chemicals, but they are generally dependent on the bioavailability of the chemical in the soil or soil solution. Information and data on chemical transfer from soils, particularly sludge-amended soils, to a variety of crop species are available in the published literature (EPA 1983, USDA 1983, DOE 1984).

A number of models are also available for determining plant uptake of contaminants from soil (Kabata-Pendias and Pendias 1984, Briggs, Bromilow, and Evans 1982, Topp et at. 1986). Root uptake of numerous contaminants, however, is inefficient and much of the contaminant concentrations found in plants results from volatilization and leaf uptake (Suter 1993). Some methods for calculating chemical concentrations in plant tissue due to root uptake and air to plant transfer are published by EPA (1990d). Other methods are available in the published literature. Quantitative structure activity relationship (QSAR) models for determining combined root and leaf uptake of organic chemicals in soils are presented by Topp et al. (1986) and Travis and Arms (1988).

4.3.3.3.4 Estimating Chemical Concentrations in Animal Prey. The animal prey that higher trophic level predators usually consume as food take up contaminants from the food chain by ingesting soil-dependent organisms (plants, soil invertebrates), lower trophic level consumers, or soil and water directly. Methods for determining BAFs or biotransfer factors to livestock tissue are available for a variety of chemicals in plants such as grain (corn, oats, wheat, etc.), forage (pasture grass, hay), and silage (EPA 1990d). Similar methods for wildlife tissue are generally not available and thus the livestock factors are sometimes used.

Models for determining the uptake and transfer of chemicals through various food chains are becoming more numerous in the literature (Winter and Streit 1992, Fordham and Reagan 1991). BAFs can oftentimes be estimated for a receptor of interest based on food chain data presented in the published literature or in studies

[11] According to EPA (1992h) guidance, the chemical concentration relating to the 95% UCL of the mean is applied as the exposure point concentration term for both the average and the reasonable maximum exposure (RME) scenarios. Although an upper bound value, this concentration is descriptive of the mean and accounts for the uncertainty associated with measurements of the "true" mean.

conducted at Superfund sites where tissue sampling was performed. Studies on the accumulation of elements by earthworms, as well as direct toxic threshold levels, are becoming more abundant due to the close association between soil contamination and earthworms and the wide variety of earthworm predators (Beyer 1990, Beyer and Stafford 1993). Several authors have published models for determining the uptake of organic chemicals by earthworms (Wheatly and Hardman 1968, van Gestel and Ma 1988, Connell 1989).

4.3.3.3.5 Bioavailability. The intake equations used in ERAs typically do not contain a factor to account for bioavailability or bioassimilation and therefore may predict an intake higher than one that would occur in actual circumstances. By not including a factor to consider bioavailability, it is assumed that 100% of the chemical detected in the medium is bioavailable (when combined with toxicity values, the risk associated with the absorption of the chemical in the animal study is derived). Modifications may sometimes be made to these intake equations to account for this factor, if the appropriate information is available.

Bioavailability refers to the ability of a chemical to be "available" in the body to interact and have an effect. There are many aspects to bioavailability; however, the type most of concern to ERAs is the ability of the chemical to be absorbed into the body. Although the medium on which the chemical is contained may be contacted, the chemical may not be absorbed for a number of reasons, including the chemical form, competition with other factors (e.g., food in the stomach), damage of the organ (e.g., stomach, lung), effect of the medium in which the chemical is contained, and others. While many of these cannot be reliably addressed in an ERA, chemical form and effect of the medium can be addressed.

The form of the chemical can affect the degree of absorption into a body. This factor is most important for chemicals that form compounds (such as metals and cyanide) and chemicals that can exist in different valence states (again, **some** metals). For example, soluble compounds of metals (e.g., barium sulfate) are readily absorbed through the stomach whereas insoluble forms (e.g., barium carbonate) are minimally absorbed. Usually, when environmental media are analyzed, chemicals are reported as an isolated entity (e.g., barium), and no information is provided on the form that existed in the medium. However, if the form of the chemical used at the site is known, and information on the absorption of that chemical form is available, the intake equation can be modified to account for a lesser absorption (see ORNL 1994). Defensible information should be available to make this modification.

The medium in which the chemical is contained also can affect the degree of bioavailability. This is most pronounced in media that demonstrate an ability to bind chemicals (such as soil and sediments). When ingested by wildlife, a competition occurs between retention of the chemical on the medium and absorption of the chemical into the body. Therefore, some of the chemical may be excreted from the body without having been absorbed and some may have been absorbed and available to exert an effect. Many factors can influence the degree to which the medium will bind the chemical, most of which cannot be reliably predicted (for example, nature of the medium [organic carbon or clay content, particle size], other chemicals being absorbed, pH, organ condition, etc.). In some instances, information may be available on the degree to which a particular medium affects specific absorption routes. If the information justifies modifying the intake equations, such a modification may be made.

In most assessments, it is generally assumed that environmental conditions are reasonably static and chemical concentrations remain constant over time, often for as long as 30 years. Such assumptions may be unreasonable. Chemical concentrations are usually reduced over time by degradation, migration, dilution, volatilization, or other removal processes. If these processes are known and can be quantified, a concentration that decreases over time can be derived for assessing intakes. If no allowances are made to decrease concentrations over time, risks will most likely be overestimated.

4.3.3.4 Exposure Characterization Summary

At the conclusion of the exposure characterization, the estimated chemical intakes for each exposed receptor group under each exposure pathway and scenario should be presented in tabular form. This presentation should include an identification of all pertinent factors (basis of exposure point concentration, use of models, if applicable, assumptions made regarding exposures, etc.). These intake estimates are combined with the COEC toxicity values, discussed in the following section, to derive estimates and characterize potential ecological risk.

Uncertainties associated with the estimation of chemical intake should be summarized at the conclusion of the exposure characterization. The basis for each uncertainty should be identified (e.g., use of a default parameter, propagation of error through multiple layers of exposure modeling), the degree of the uncertainty qualitatively

(low, medium, or high) or quantitatively estimated, and the impact of the uncertainty qualitatively (overestimate and/or underestimate) or quantitatively stated. Description and presentation of uncertainties are discussed further in Section 4.5.2.

4.4 Analysis Phase-Ecological Effects Characterization

The ecological effects characterization (toxicity assessment) includes a preliminary evaluation of chemical-specific ARARs, a summary of the types of adverse effects on biota associated with exposure to site-related chemicals, relationships between magnitude of exposures and adverse effects, and related uncertainties for chemical toxicity, particularly with respect to site biota. Ecological receptor health effects are characterized using EPA-derived critical toxicity values, when available, in addition to selected literature pertaining to site- and receptor-specific parameters.

The preliminary toxicity evaluation provides toxicological profiles centered on health effects information on site biota. The profiles cover the major health effects information available for each COEC. Data pertaining to site-specific species are emphasized, and information on domestic or laboratory animals is used when site-specific biota data are unavailable. Adequacy of the existing database is also to be evaluated as part of this task.

4.4.1 Objectives

The Tier I effects characterization fulfills two specific objectives in a risk assessment. First, available toxicological literature is reviewed to identify appropriate literature benchmark values to use. The toxicological literature forms the basis for developing summaries of the potential toxicity of the COECs for inclusion in the risk assessment. Second, appropriate reference toxicity values (RTVs) (EPA 1993e; also abbreviated TRVs by other authors) are developed using literature benchmark values and uncertainty factors to estimate potential ecological risks associated with key receptor chemical exposure. This is accomplished by reviewing the available information on COEC toxicity and summarizing the factors pertinent to the exposures being assessed. In the following sections, each of these components of the effects characterization is discussed.

The Tier I effects characterization is based on a desk-top hazard index (HI) or hazard quotient (HQ) approach. Numerous bioassessment tools,[12] however, are available to the risk assessor to employ for directly measuring or investigating toxicity, or even risk. While these bioassessment techniques are presented as a Tier II effort in this manual (see Chapter 5.0), it is advisable to consider these techniques early on in the planning process as a potentially expedient means to directly address the assessment endpoints, particularly in aquatic ecosystems. Bioassessment techniques offer several advantages over the HQ or model approaches to toxicity estimation: they

- Demonstrate whether the COECs are bioavailable.
- Evaluate cumulative impacts due to exposure to multiple COECs.
- Evaluate toxicity of COECs for which no RTVs can be found.
- Characterize the nature of the toxicity.
- Integrate media variations and spatially characterize toxicity.
- Monitor impacts before and after remediation.
- Develop remedial levels in terms of toxicity and then monitor effectiveness and success of remedial actions.

4.4.2 Sources of Literature Benchmark Values

The sources that should be consulted for literature benchmark values will vary with the type of organisms being used as ecological receptors (e.g., aquatic, terrestrial) and the level of effort (i.e., tier). If the level of effort (time and money) is limited as is the case in Tier I and possibly Tier II, then documents that summarize available ecotoxicological information will suffice. If a higher level of certainty in the data is an objective in the compilation of literature benchmark values, then the primary toxicological literature should be sought so that details of the toxicity test conditions can be reviewed, validity of the test results confirmed, and applicability to site conditions determined.

[12] An in-depth discussion of topics related to the use of bioassessment approaches in ERAs is available in the September 1994, Volume 2 series of *Eco Updates.*

Toxicologic information on chemicals in aquatic ecosystems is fairly plentiful, while that for terrestrial ecosystems is somewhat more limited. Most of the available toxicological information for soil-based exposures has been generated using soil-dependent biota. ORNL (1994) however, has recently published benchmark values for plants, sediment-associated biota, and terrestrial wildlife. Compilations of toxicological data for soil-dependent organisms (plants, invertebrates, and microbes) are available in the open literature (Hulzebros, Adema, and Dirven-Van Breeman 1993, Kabata-Pendias and Pendias 1984, USFWS 1990, Overcash and Pal 1979, Gough, Schacklette, and Case 1979, Callahan, Shirazi, and Neuhauser 1994). PHYTOTOX, a database dealing with the effects of organic and inorganic chemicals on plants, is also available for government, academic, and industrial users (Royce, Fletcher, and Risser 1984). A new EPA database, ECOTOX, which integrates aquatic and terrestrial receptor databases is expected to become available in late-1995 (see Appendix B, Information Sources).

Published ERAs, such as those reviewed in EPA (1993f) *Case Studies from a Risk Assessment Perspective,* offer additional sources of terrestrial and aquatic toxicity data. Toxicity data and information for developing wildlife RTVs also may be obtained from many of the same sources used for human health toxicity information, particularly where data on small mammals (rats and mice) are needed. Regional EPA and DoD (U.S. Army, U.S. Navy) BTAG/ETAG persons can also be contacted for assistance. Other sources for aquatic and terrestrial laboratory data are presented in Appendix B and include the following:

- EPA Criteria Documents. Include ambient water criteria documents, proposed sediment quality criteria documents, drinking water criteria documents, air quality criteria documents, and health effects assessment documents.

- USFWS Contaminant Hazard Reviews. (Author: R. Eisler, dates 19851994). This is a series of reports reviewing the hazards of over 25 metals and organic compounds to fish, wildlife, and invertebrates.

- Oak Ridge National Laboratory (ORNL 1994), Toxicological screening benchmarks for ERAs (available in PC-database). This series of reports includes benchmarks for terrestrial wildlife, terrestrial plants, sediment-associated biota, and aquatic biota, and soil and litter invertebrates and heterotrophic processes.

- Toxicological Profiles developed by the Agency for Toxic Substances and Disease Registry (ATSDR 1989).

- Aquatic and terrestrial toxicological data (and in some cases, literature citations). Available in public or on-line databases such as Toxline, BIOSIS, AQUIRE, ASTER, QSAR, HSDB, Ecological Abstracts, Biological Abstracts, Current Contents, Duckdata (USFWS).

- National Academy of Sciences publications such as *Mineral Tolerance of Domestic Animals* (1980).

- Integrated Risk Information System (IRIS). This is EPA's primary database for the reporting of up-to-date human health toxicity values that have been verified by the EPA. IRIS may be accessed through TOXNET and other commercial services. IRIS contains numerous chemical profiles that present verified chronic reference doses for laboratory animals. The study(s) from which the toxicity value was derived is summarized, and the method of derivation is explained (e.g., applied uncertainty and modifying factors, level of confidence, extrapolation model).

- Health Effects Assessment Summary Tables (HEAST). HEAST is published annually by EPA, and is a collection of interim and provisional toxicity values developed by EPA. Verified toxicity values are not presented in the most current version of HEAST: rather, the user is directed to IRIS. HEAST can be obtained through the National Technical Information Service (NTIS).

4.4.3 Selection of Literature Benchmark Values

Laboratory animals (rat and mouse) studies are generally classified by the U.S. Dept. of Health and Human Services (USDHHS) according to exposure duration: chronic (>365 days), intermediate or subchronic (15-364 days), and acute <14 days). In aquatic bioassay tests, test durations for acute toxicity tests are typically 48 hours for invertebrates and 6 hours for fish. Definitions of the terms chronic, subchronic, and acute, however, are often inconsistent, and depend on the organism being tested. Suter (1993) and EPA (1995b) arbitrarily consider chronic to be 10 percent of the organism's lifespan. According to EPA's health effects testing guidelines, chronic toxicity

tests should involve dosing over a period of at least 12 months. The organisms studied and study duration should be reported when compiling literature benchmark values.

In selecting data to be used in the derivation of the RTV, the nature of the observed endpoints is the primary selection criterion. Literature benchmark values which best reflect potential impacts to wildlife populations through resultant changes in mortality and/or fecundity rates should be used. Toxic responses such as elevated enzyme levels (e.g., elevated blood aminolevulinic acid dehydrase [ALAD] from exposure to lead) or increased tissue concentrations, while they may serve as good biomarkers indicative of an organisms's exposure, are not useful endpoints insofar as being relevant and indicative of adverse impacts to key receptor populations. Relevant intermediate and chronic endpoints are those which affect organismal growth or viability, or reproductive or developmental success, or any other endpoint which is, or is directly related to, parameters that influence population dynamics. The toxic effect manifested at the lowest exposure level is (generally) selected as the critical effect. For some ERAs, however, the lowest acute level also is selected for use in determining an acute RTV. Where the toxicity database is large enough, a dose-response curve may be generated and used as the basis to select a literature benchmark value or to determine the RTV.

The following factors should be considered when selecting literature benchmark values and developing RTVs for use in the risk assessment:

- Literature benchmark values should be obtained from bioassays having test conditions as similar as possible to onsite conditions. For example, water hardness, which affects the toxicity of many metals, should be the same in order to have the bioassay results applicable to site conditions.

- The literature benchmark values and RTV should correspond to the exposure route being assessed: in ERAs, this is most typically the oral exposure route (dermal exposure may be assessed using modified oral toxicity values).

- The RTV should be appropriate for the key receptor and toxicity endpoint being assessed: e.g., assessment of reproductive and developmental effects in mammals and birds would require at least two, but possibly four, RTVs. RTVs for different toxicity endpoints in different receptors or receptors groups may need to be developed.

- The literature benchmark value and RTV should correspond to the appropriate exposure duration period: subchronic (two weeks to one year) or chronic (greater than one year).

- The literature benchmark value and RTV should correspond to the chemical form being assessed (only applicable to some chemicals, but especially metals such as chromium [trivalent or hexavalent] and mercury).

The process for selecting benchmark toxicity values is flexible so that site-specific considerations can be incorporated. Careful consideration should be given to the development of benchmark toxicity values, as they may provide the preliminary information used to set the target cleanup levels at sites where remedial action is anticipated. In the Tier I HI or HQ approach, the RTV is essentially the measurement endpoint and the hazard ratios calculated are inherently no more protective than the nature of the toxic mechanism described by the RTV. Caution should be taken in the assessment and selection of the RTV. For example, if the RTV were based on "acute" lethality, it would not be protective of chronic exposure conditions.[13]

4.4.4 Development of Reference Toxicity Values

Determination of RTVs for terrestrial and aquatic organisms is dependent on both life style and life stage. Literature benchmark values and RTVs for organisms in aquatic ecosystems (e.g., benthic macroinvertebrates and fish) are generally concentration-based, but can be dose-based for amphibians and higher trophic level receptors (waterfowl and aquatic mammals). Amphibian exposure is perhaps the most difficult to quantify, as amphibians have both concentration-based aquatic life stages and dose-based terrestrial life stages. Terrestrial RTVs can also be either concentration-based (e.g., flora and soil invertebrates) or dose-based (e.g., vertebrate fauna).

[13] As Tier I assessment endpoints are typically phrased in terms of protecting populations, the RTVs focus on measures of growth, survival, and reproduction. Under some circumstances, it may be appropriate to protect lower levels of biological order and employ biomarkers as benchmark values. Additionally, certain biomarkers are indicative of conditions which have direct implications to assessment endpoints of growth, survival, or reproduction and are not merely exposure markers.

Federal AWQC are frequently used as the equivalent of an RTV for aquatic organisms. On some sites, AWQC may be judged to be overly cautious RTVs for the specific key receptors, if the organisms on which the AWQC are based are far more sensitive than any onsite receptors.

In these cases, toxicity information used to develop the original AWQC may be used in conjunction with **other** toxicity data and literature benchmark values to develop a more site- and receptor-specific RTV.

In terrestrial ecosystems, two types of RTVs are needed: concentration-based RTVs for soil-dependent organisms and dose-based RTVs for wildlife. RTVs for soil-dependent organisms (e.g., plants, earthworms) are similar to AWQC in that they are concentration based. RTVs for wildlife are similar to the critical toxicity values (reference doses) used in human health risk assessments. Unlike human health toxicity values, however, RTVs for terrestrial wildlife are generally not available and thus need to be developed by the risk assessor. In order to appropriately select and use RTVs and to identify assumptions and uncertainties associated with RTVs, an understanding of the general practice currently followed in selecting RTVs is needed. Site-specific RTVs for aquatic and terrestrial ERAs should be developed in consultation with local wildlife and regulatory agencies.

4.4.4.1 Development of Aquatic RTVs

As stated above, aquatic RTVs can be based on state or Federal AWQC. However, especially in the case of metals, toxicity can be significantly affected by site-specific factors. Factors that can affect site-specific values include: ambient water chemistry, different patterns of toxicity for different metals, metals fate and transport, and use of standardized protocol for clean and ultraclean metals analysis. Also, applicability of the chronic criterion or acute criterion to the species of concern should be confirmed. Because AWQC have been calculated to protect populations of the most sensitive aquatic species, these criteria may be over (or under) protective of the aquatic ecological receptor(s) selected for the risk assessment. Methods used to calculate AWQC are described in Appendix A of the "Gold Book" (EPA 1986b) and more recently in the EPA's *Water Quality Standards Handbook* (EPA 1993g) and *Interim Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria* (EPA 1992j, 1993c, 1995f). To determine the basis for a particular chemical, the AWQC document for that metal or compound should be consulted. As is the case with literature benchmark values, use of AWQC for RTVs may involve division of the criterion by uncertainty factors to account for greater sensitivity or uncertainty regarding the selected site receptor as compared to the AWQC species tested, life stage, test endpoint, and test duration. In the case of metals, the basis (total, total recoverable, or dissolved concentration) for the RTV or criterion and the chemical concentrations to which it is compared should be verified and consistent.

4.4.4.2 Development of Terrestrial RTVs for Soil-Dependent Organisms

EPA is currently evaluating the development of standardized protocol for deriving ecological effects-based soil criteria for contaminated sites. EPA plans to use an approach similar to that used for calculating sediment quality guidelines for the National Status and Trends Program (NSTP) (Long and Morgan 1990). This method uses a percentile of the effects data set or combined effects and no effects data set to estimate a concentration in the sediment expected to cause no adverse biological effects.

ORNL (1994) has published two documents containing benchmarks useful for screening potential COEC effects on terrestrial plants and litter invertebrates/heterotrophic processes (e.g., soil- and litter-dwelling invertebrates, including earthworms, other micro- and macroinvertebrates, or heterotrophic bacteria and fungi).

Countries outside the U.S. (Canada, Netherlands) have developed various cleanup criteria for soils. Most of these criteria are with respect to groundwater protection although some countries (e.g., Canada) have developed a limited number of soil criteria based on phytotoxicity and animal health (ASTM 1995).

4.4.4.3 Development of Terrestrial RTVs for Wildlife

Two general steps are performed in the derivation of RTVs for terrestrial wildlife: a hazard identification and **a** dose-response evaluation. A hazard identification is a qualitative assessment that determines whether exposure to a chemical can cause an increase in the occurrence of a particular adverse effect in the key receptors. A hazard identification includes a review of the physical and chemical properties of the chemical, examination of typical routes of exposure, and a review of the toxicologic effects of the chemical (acute, subchronic, and chronic).

When a chemical has been identified as potentially producing adverse health impacts on wildlife, a dose-response evaluation is performed that quantifies the relationship between the dose or exposure to a chemical and the

incidence of adverse effects. The available data are reviewed from a number of viewpoints, and the study or studies that best describe the potential toxicity of the chemical are selected as the basis for deriving a quantitative description of the chemical's toxicity. Uncertainty factors or extrapolation models are commonly applied to transform the dose-response relationship observed in an experimental study to one that can be used to describe potential wildlife exposures to environmental media.

Central to the determination of the RTV is the evaluation of the threshold or exposure level that must be exceeded for the adverse impact of the chemical to manifest itself. Below this threshold, factors such as the body's protective mechanisms (e.g., metabolism, elimination) can handle the chemical, preventing expression of adverse effects. The basis of the derivation of the RTV, then, is to identify this threshold level, and modify it to express potential toxicity to a wildlife population. In deriving the RTV, however, it is important to examine both LOAEL and NOAEL values in order to select the most reasonable endpoint and benchmark value that is protective of the more sensitive receptors without being overly conservative.[14]

Derivation of an RTV for ecological receptors is similar to derivation of a reference dose (RfD) for humans. An RTV may thus be similarly defined as "a provisional estimate of a daily exposure to the ecological receptor population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a portion of a lifetime, in the case of a subchronic RTV, or during a lifetime, in the case of a chronic RTV" (EPA 1992k).

To develop a chronic RTV, available toxicological studies are reviewed and a critical literature benchmark study (or studies) is selected as the basis for the RTV. Depending on the types of key receptors for the site, literature studies on a variety of organisms may need to be reviewed. The selection of a critical study or studies and their benchmark values is made by professional judgment, but includes consideration of study quality, relevance of the study to wildlife exposures, and other factors. Field studies, as well as laboratory studies are useful in the RTV determinations. Often field studies provide key ecological information showing that while the chemical elicits a toxic response in laboratory studies, it may not necessarily elicit similar results under field conditions. When laboratory studies are used, preference may be given to laboratory studies with wildlife species over traditional laboratory animals to reduce uncertainties in making interspecies extrapolations.

The highest level of exposure associated with the NOAEL or LOAEL is identified (i.e., the literature benchmark value).[15] A NOAEL or LOABL value is preferred over a lethal dose value for calculation of the RTV. In order to compare benchmark values, dietary concentrations (mg/kg) must be converted to dose values (mg/kg-bw), so that dose is not under- or overestimated when applied to organisms consuming different amounts of food per body weight. Average ingestion rate and body weight for a species (and life stage) are reported in relevant studies or may be obtained from various literature sources (EPA 1993e, Appendix B).

Where lacking, chronic NOAEL RTVs may be generated for a species of concern by applying "safety factors" (also called uncertainty or modifying factors) to available toxicity data on a specific COEC. Specific methodologies for deriving RTVs have been published by EPA (1995b), Newell, Johnson, and AlIen (1987). and USAERDEC (1994). Application of safety factors represents a specific area of uncertainty inherent in the extrapolation of experimental laboratory data to wildlife and should be evaluated for its eventual impact on risk estimation. To derive an oral RTV, the NOAEL or LOABL may be divided by various uncertainty factors as shown below:

$$RTV = \frac{\text{NOAEL or LOAEL}}{UFs_s \times UF_c \times UF_e \times UF_i}$$

[14] Selection of a conservative literature benchmark value when combined with conservative uncertainty factors can lead to the development of an RTV that is far below that of typical background concentrations (inorganics). Use of such RTVs, when combined with reasonable bioconcentration factors, to estimate intake for lower trophic level receptors sometimes indicates that the background concentrations pose extreme and unrealistic hazards. Caution, accompanied by an appropriate uncertainty discussion, should be used in developing RTVs.

[15] NOAELs and LOAELs ate artifacts of the specific dosing regime employed in the individual toxicity studies and can vary considerably from study to study. Despite the connotations associated with the acronyms, these values do not represent actual threshold levels for toxicity. Therefore, their use in selecting benchmark values or RTVs introduces an additional element of uncertainty.

The uncertainty and modifying factors used by EPA include the following:

- UF_s = an intertaxon uncertainty factor between 1.0 and 100 for extrapolating toxicity data across test species. Also called a species sensitivity factor (SSF), this adjustment may be necessary where toxicity information does not include representative wildlife species or the species identified as requiring greater protection. If data are from numerous species and represent the most sensitive mammalian and avian species, the SSF may be equal to 1.0. Caution should be taken in using uncertainty factors to extrapolate across widely disparate taxonomic groups; e.g., birds to mammals and vice versa.

- UF_c = an uncertainty factor between 1.0 and 10 for subchronic to chronic exposures. This factor may be used when assessing highly bioaccumulative chemicals, where toxicokinetic considerations suggest that a bioassay of limited length may underestimate hazard.

- UF_e = an uncertainty factor between 1.0 and 10 for LOAEL to NOAEL extrapolations.

- UF_i = an uncertainty factor of 10 for intraspecies toxicological differences to protect, in special cases, sensitive individuals rather than a population. Also called an intraspecies uncertainty factor (ISF).

Values other than 1.0 (or maximum values) would rarely if ever be used for all uncertainty factors simultaneously (EPA 1995b), as this tends to result in an unreasonably conservative benchmark value. Also, where an intermediate uncertainty factor is to be applied, a value of 3.0, based on a logarithmic scale, can be applied rather than a 5.0, based on a linear scale (EPA 1995b). An additional modifying factor between 0 and 10 may also be applied, if it is judged to be necessary, to account for miscellaneous factors not specifically addressed by the above four uncertainty factors. An example of the process for developing an RTV for a small mammalian receptor is shown in CS 12.

Guidance as to the determination of the magnitude of the numerical value to be assigned to each uncertainty factor is lacking for ERAs. For further guidance on selection of an appropriate uncertainty factor, the risk assessor should consult the regional EPA or DoD (U.S. Army, U.S. Navy) BTAG/ETAG experts. Typically, separate RTVs are developed for large mammals (herbivores/carnivores), small mammals (rodents), and birds.

4.4.4.4 Use of an Acute to Chronic Conversion Ratio

In some cases, chronic toxicity data are not available and an acute/chronic ratio must be applied to acute toxicity data (typically mortality) to estimate chronic effects levels. Because wildlife toxicity databases are fairly limited, use of a factor for extrapolating from acute data to chronic data will likely be large and result in an overly conservative RTV.

4.4.4.5 Short-Term Critical Toxicity Values

Certain exposures, such as during construction or remediation activities, may occur only for a brief time. Likewise, exposure of mobile wildlife to site contamination may be brief and intermittent. These exposures require the use of short-term or acute toxicity values. In most cases, risk assessments are concerned with longer exposures that are appropriately addressed by subchronic or chronic RTVs. Applying these values, however, to very short-term exposures (less than two weeks) may not be valid. Results of primary toxicology studies should be used in evaluating potential effects of short-term chemical exposures. Direct comparisons should be made cautiously, however, because of the limitations of single study results. The uncertainties and assumptions involved in the use of acute RTVs should be clearly stated in the assessment.

4.4.4.6 Feeding and Drinking Rates

When drinking and feeding rates and body weight are needed to express the NOAEL or LOAEL in mg/kg-bw/d, they should be obtained from the literature benchmark study from which the NOAEL or LOAEL was derived. As noted earlier, dietary chemical concentrations in mg/kg must be normalized for body weight and food intake of the test organism and receptor of concern before they can be used as a screening benchmark.

Depending on the organism and study, dry weight chemical concentrations may also need to be converted on a wet-weight basis. Use of wet weight versus dry weight in estimating dietary exposures can be problematic, particularly where the moisture content of the diet is highly variable (e.g., in plants). Dietary concentrations in most toxicological studies are reported on a wet-weight basis. However, moisture content of laboratory diets is

CASE STUDY 12

DERIVATION OF A SMALL MAMMAL RTV FOR ACETONE

The following describes the process for deriving a site-specific reference toxicity value (RTV), in this case for small mammal receptors that ingest site soil.

Selection of Literature Values

The toxicological data for acetone are assembled from available literature sources and screened to select the lowest LOAEL and highest NOAEL literature values (mg/kg-bw/day) for chronic (long-term) effects, if available.

The literature values collected are shown below:

TOXICITY DATA FOR ACETONE

Test Species	Form	Duration	Effect level/Effect	Dietary (mg/kg-food)	Dose (mg/kg-bw/day)	Reference
MAMMALS						
Rat	–	13 weeks	NOAEL/ respiratory, cardiovascular, gastrointestinal, musculoskeletal, hepatic, dermal, body weight effects	–	3,400	NTP 1991, Dictz et al. 1991
Rat	–	14 days	LOAEL/bone marrow hypoplasia	–	6,942	NTP 1991, Dietz et al. 1991
Rat	–	14 days	NOAEL/hepatic, renal, body weight effects	–	8,560	NTP 1991, Dietz et al. 1991
Rat	–	13 weeks	LOAEL/reproductive effects	–	3,400	NTP 1991, Dietz et al. 1991
Mouse	–	14 days	NOAEL/renal, body weight effects	–	12,725	NTP 1991, Dietz et al. 1991
Mouse	–	14 days	LOAEL/hepatic effects	–	3,896	NTP 1991, Dietz et al. 1991

LOAEL - Lowest observable adverse effects level
NOAEL - No observable adverse effects level

Reference Toxicity Value

Each selected literature value is then divided by a conservative total uncertainty factor to calculate a long-term RTV that is used to screen measured surface soil and dietary concentrations in order to determine whether acetone may need to be evaluated further. The total uncertainty factor is the product of one or more separate uncertainty factors for each of two sources of uncertainty: (1) study duration and (2) study endpoint. Within the study endpoint category, two toxicity test endpoint categories are listed: nonlethal effects (e.g., a change in fecundity) and lethal effects (i.e., some level of reported mortality). A frank effect level is the concentration of a chemical that causes an obvious deleterious effect; the lethal frank effect level is the LD_{50} concentration (a concentration or dose that is lethal to 50% of animals in the study). The uncertainty values assigned to each category are described below:

UNCERTAINTY FACTOR PROTOCOL FOR LONG-TERM REFERENCE TOXICITY VALUES

Basis for Uncertainty		Uncertainty Value Assigned
Study Duration Category		
Chronic studies where contaminants attained equilibrium		1
Chronic studies where equilibrium not attained or possibly not attained, including subchronic studies		5
Acute studies (7 to 14 day, 2 to 7 day, 1-day single dose)		10, 15, 20
Study Endpoint Category**	**Nonlethal**	**Lethal**
No observed effects level	NOEL: 1	NOEL: 3
No observed adverse effects level	NOAEL: 1	NOAEL: 3
Lowest observed effects level	LOEL: 3	LOEL: 10
Lowest observed adverse effects level	LOAEL: 5	LOAEL: 10
Frank effects level	FEL: 10	FEL: 15

** To estimate an appropriate NOAEL

REFERENCE TOXICITY VALUES

A summary of the information used to derive the RTV for acetone is presented next. The two uncertainty factors most applicable to the toxicological study were selected, combined, and then divided into the selected literature value. The resulting RTV dose (mg/kg-bw/day) is used in the conservative risk screening for comparison to the site-specific surface soil dose (mg/kg-bw/day) to determine if acetone may need further evaluation.

LONG-TERM REFERENCE TOXICITY VALUES

Chemical (COC)	Species	Literature Value: Dose (mg/kg-bw/day)	Literature Value: Effect Level	Study Duration Uncertainty	Study Endpoint Uncertainty	Total Uncertainty Factor	Reference Toxicity Value (RTV) (mg/kg-bw/day)
Acetone	Rat	3400	NOAEL	5	1	5	680

also typically less than 10 percent, so this difference is sometimes ignored (Beyer and Stafford 1993). The risk assessor should, at a minimum, strive to be consistent (or conservative) in reporting between wet weight when comparing the RTV to the exposure intake value in the risk calculation. The basic equation for converting tissue analyte concentration between dry and wet weight samples is

Wet weight tissue concentration = dry weight tissue concentration x (% solid/100).[16]

where % solids = 100 - % moisture

If the literature benchmark study does not provide the needed values, they should be determined from appropriate data tables for the particular study species. For studies done with domestic laboratory animals, RTECS (NIOSH 1987 or latest edition) can be consulted. When insufficient data exist for other mammalian or avian species, the allometric equations from Calder and Braun (1983), Nagy (1987). and EPA (1988k, 1993e) can be used to calculate feeding and drinking rates (Exhibit 15). Reference food and water intake values for a variety of wildlife are also provided in ORNL (1994).

4.4.5 Additional Considerations in Developing RTVs

There are a number of additional factors that should be considered when conducting the effects characterization, reviewing the toxicological literature, and determining RTVs. These are discussed in the following sections.

4.4.5.1 Absorption Considerations

Most toxicity values are based on administered, rather than absorbed, doses, and the absorption efficiency has not been considered. However, whatever absorption has occurred during the toxicological study is inherent in the toxicity value. Therefore, use of a toxicity value assumes that the extent of absorption observed in the study is also appropriate for the exposure pathway being assessed. Differences in absorption efficiencies between that applicable to the RTV and that being assessed may occur for a number of reasons. Two factors that will influence absorption efficiencies are differences in chemical form and differences in the exposure medium.

The form of the chemical used in the literature benchmark wildlife study may not be the same as the chemical form present in the environmental medium being assessed, and may be absorbed to a different degree. Therefore, use of the toxicity value may over- or underestimate the actual absorption potentially occurring in receptors. This is especially important for certain metals where inorganic forms (e.g., metallic lead) differ widely from organic forms (e.g., lead acetate) in their potential toxicity. The basis of the chemical's RTV should be reported in the effects characterization and compared with the form (if known) in the site media. Often the form in site media is not known, but can sometimes be inferred based on site history or by the medium in which the chemical is found (for example, a metal in soil is unlikely to be present in its soluble form).

In toxicity studies, chemicals are often administered in drinking water, mixed with food, or mixed in an administration vehicle such as olive oil to facilitate absorption. In environmental settings, exposure to chemicals may occur in a medium similar to that used in the study (e.g., in drinking water) or in a medium quite different from that used in the study (e.g., the soil matrix). Certain media, particularly soil and sediments, may bind chemicals, reducing the amount that is available for absorption (i.e., bioavailability). In these instances, it may be appropriate to reduce the COEC intake value in the exposure calculation with a matrix effects or bioavailability factor to account for this binding (see Section 4.3.3.3.5).[17]

[16] Given a 230-mg/kg wet weight of lead in plants and a 20% moisture content, the dry weight concentration would be 287.5 mg/kg.

[17] Numerous studies show that not only metals but organic chemicals, including pesticides, bind tightly to soil, reducing their bioavailability through both oral and dermal exposure. Calderbank (1989) showed that clays and organic colloids have a large surface area and cation exchange capacity, which permit significant adsorption of virtually all classes of pesticides: furthermore, the adsorbed fraction (20% to 70%) desorbs slowly and is effectively a bound fraction that increases over time as the soil-pesticide bond "ages." Shu et al. (1988) reported a bioavailability range of 25 to 50% for TCDD to rats from soils at Times Beach, Missouri. Goon et al. (1991) showed that benzo(a)pyrene (BaP) that had aged 6 months in soil was only 34 and 51% orally bioavailable for clayey and sandy soils, relative to BaP administered alone to rats. In general, differences in absorption between lab media and site media should not be assumed, unless there's adequate information to the contrary.

4.4.5.2 Assessment of inhalation Exposure Route for Wildlife

Inhalation exposure routes are generally not addressed in ERAs due to the lack of toxicity information for wildlife species and the lesser significance of the inhalation exposure route to the oral ingestion route." In general, VOC concentrations of 100 ppm or greater in air are needed to induce toxic responses in laboratory rats and mice from inhalation (NIOSH 1987). Concentrations in soils would have to be many times greater than this to produce these toxic levels in air, even near the soil surface.

In order to quantitatively evaluate this exposure route, the risk assessor may need to consider factors such as the target species' airway size, branching pattern, breathing rate (volume and frequency), and clearance mechanisms, whether the contaminant is a gas or aerosol, whether the chemical's effects are systemic or confined to the respiratory tract, as well as particle size distribution, temperature, and vapor pressure, and pharmacokinetic data (EPA 1993e). In addition, the dose deposited, retained, and absorbed in the respiratory tract is a function of species anatomy and physiology as well as physicochemical properties of the contaminant, Allometric equations are available from EPA (1993e). A procedure for calculating inhalation exposure is also published by USDOI (1991).

Total petroleum hydrocarbon (TPH) contamination is one example where the inhalation of volatiles for small, burrowing animals is of concern in the ERA. W. Kappleman in Maughan (1993) provides a methodology for determining ecological effects levels for muskrat and beaver via inhalation and dermal exposure pathways for benzene, toluene, ethylbenzene, total xylenes (BTEX), and PAHs. These methodologies may be applied where site-specific conditions require inhalation exposure to be considered an important exposure route. The methodology for calculating inhalation concentrations for humans as discussed in EPA's (1990e) *Interim Methods for Development of Inhalation Reference Concentrations* may be followed to some extent.

[18] A notable exception is the great number of studies conducted on response and uptake by birds and mammals from aerial pesticide spraying on agricultural crops.

4.4.5.3 Assessment of Dermal Exposure Route for Wildlife

Dermal exposure routes are generally not addressed in ERAs due to limited toxicity information for terrestrial wildlife species and the lesser significance of the dermal exposure route to the oral ingestion pathway. The dermal pathway may be of importance where wildlife are directly sprayed or frequent areas with surface-contaminated vegetation or where the animals are burrowing in contaminated soils/sediments.

Wildlife are generally assumed to be protected by their fur, feathers, or scales, which prevent a chemical from reaching an animal's skin and may allow the chemical to dry or to be rubbed off during movement. Dermal absorption of contaminants is a function of chemical properties of the contaminated medium, the permeability of the receptor's outer covering, area in contact with the contaminated medium, and the duration and pattern of contact. The methodology for calculating dermal exposure concentrations for humans is discussed in EPA's (19921) *Dermal Exposure Assessment: Principles and Applications* and may be followed to some extent where dermal exposure concentrations for wildlife need to be calculated.

Dermal exposures may be of concern for wildlife that swim or burrow. Mammals and birds groom themselves regularly and may receive an oral ingestion dose from dermal contamination of their fur or feathers. An oral ingestion dose for animals which groom themselves may be calculated based on a methodology published by USDOI (1991) for determining dermal exposure to representative western rangeland wildlife species from herbicide sprays. W. Kappleman in Maughan (1993) provides a methodology for determining ecological effects levels for muskrat and beaver via dermal exposure pathways for BTEX and PAHs. Such a methodology may be applied where site-specific conditions require dermal exposure to be considered an important exposure route.

4.4.5.4 Body Scaling Factors

In the ORNL (1994) document, body scaling factors are applied to derive screening toxicity benchmark values for various sized organisms, based on a select reference

toxicity value. Application of a 2/3 or 3/4 exponential factor for wildlife is based on the human health practice of applying an exponential factor of 2/3 in adjusting animal data to an equivalent human dose. Wildlife toxicologists, however, commonly scale dose to body weight when deriving benchmark values without incorporating this exponential factor.

4.4.6 Special Chemicals

Some commonly detected chemicals require special consideration in the generation of an RTV (e.g., their potential to biomagnify, need for a surrogate component evaluation, difficulty in obtaining toxicity information) or have specific chemical forms that greatly influence bioavailability and toxicity. The following chemicals are discussed in this light:

- Metals.
- Polycyclic Aromatic Hydrocarbons (PAHs).
- Organochlorine Pesticides (OCPs) and Polychlorinated Biphenyls (PCBs).
- Chlorinated Dibenzo-p-dioxins and Dibenzofurans (CDDs/CDFs).
- Total Petroleum Hydrocarbons (TXH) and other petroleum groupings.
- Military chemicals.

4.4.6.1 Metals

The toxicity of metals depends foremost on chemical form. For example, chromium (+3) occurs naturally and is common in the environment and has a relatively low toxicity. Chromium (+6) is largely related to anthropogenic releases and is very toxic, but is readily reduced in the environment to chromium (+3). Organometallic forms (methylmercury, alkylead) are more toxic than the elemental forms. Much of the literature does not specify the chemical form of an element when discussing its toxicity to biota. It may be assumed in these instances that only the total concentration of the metal was known.

To be toxic an element must be available to the receptors. In order for this to occur, the chemical must exist in a form that can enter tissues of the organisms. Total amounts of a chemical in the environment are not relevant to an adequate estimation of toxicity hazard unless it can be shown that the element exists in, or is likely to assume, an available form under the environmental conditions in which it occurs, and animals or plants are likely to contact this form either directly or indirectly (Gough, Shacklette, and Case 1979).

Aquatic Organisms and Metals

The site-specific toxicity of a metal to aquatic organisms depends on the physical form of the metal, the effect of other metals and organic compounds (anthropogenic and naturally occurring) in the water, as well as the chemical or ionic form of the metal of interest. Metals results from surface water analyses can be reported in terms of the total recoverable metals, total metals, acid soluble metals, or dissolved metals. All four methods measure all of the dissolved metal present but differ (because of varying field or laboratory procedures) in the amount of particulate metal measured. While Federal AWQC are reported as total recoverable metals, many states have standards based on dissolved metals. The basis and form (dissolved versus total) of the specific criteria should be verified before being applied at a site. The risk assessor may also need to take into account transformation of onsite metals to bioavailable forms with migration offsite.

In order to develop a better understanding of metals criteria, bioavailability, and toxicity, EPA has issued a series of guidance documents (EPA 1992j; 1993c; 1995f) to supplement the *Water Quality Handbook* (EPA 1993g). These documents describe:

- Relationships among the various physical forms reported in water quality results.
- The importance of site-specific bioassays (if this level of effort is justifiable) to create a WER to account for the fact that in situ metals toxicities are frequently less than reported from laboratory bioassay tests.
- Observed ratios between dissolved metals and total recoverable metals in order to facilitate interpretation of AWQC and the more bioavailable dissolved metals.

Plants and Metals

Plants are intermediate reservoirs through which trace metals from primary sources move to other living things. Plants may be passive receptors of trace metals, as in root adsorption, or they may accumulate and store metals in nontoxic forms for later distribution and use (Tiffin 1977). A mechanism of tolerance in some plants apparently

involves binding of potentially toxic metals at the cell walls of roots and leaves, away from sensitive sites within the cell. The metal forms which occur in plants appear to have a decisive role in metal transfers to other organisms (Tiffin 1977).

There are a large number of processes that operate to regulate metal cycling, including ion exchange, adsorption, formation of organic complexes, and precipitation. All these have different and often opposing effects: and all are very dependent on pH and other soil/sediment characteristics. Since site conditions vary so much in these respects, both spatially and temporally, metal reactions and fates often vary. In addition to environmental variability, there are differences due to plant physiology and genotype (Outridge and Noller 1991). Therefore, it is very difficult to extrapolate from one study location or plant to another.

As described in Dunbabin and Bowmer (1992) there are some general trends that have been noted. Potential bioavailability generally increases with increases in acidity, reducing power, salinity, and concentration of organic ligands. However, if sulfur is present, a reducing environment will result in the production of insoluble metal sulfides. Other specific factors that influence bioavailability include sediment size (clay provides more surface area for adsorption and reactions), presence of hydrous iron and manganese oxides (which adsorb metals), and the nutrient regime (which, for example, affects the ability of microbes to transform elemental mercury to methylmercury) (Stewart, Haynes, and Martinez 1992).

Terrestrial Fauna and Metals

Several metals, while potentially toxic, are also essential micronutrients for plants and animals, e.g., zinc, selenium. All metals, whether essential or nonessential, can adversely affect terrestrial organisms, if included in the diet at excessively high levels. In general, tolerance levels vary from animal to animal and even from day to day in a single animal (NAS 1980). Many factors, such as age and physiological status of the animal (growth, lactation, etc.), nutritional status, levels of various dietary components, duration and route of exposure, and biological availability of the compound, influence the level at which a metal may cause an adverse effect in the organism (NAS 1980). Exposure of animals to excessively high concentrations of metals can result in acute signs of toxicosis, which may be quite different from the chronic effects displayed after the metal has been ingested at higher than normal levels over an extended period of time. Metals that biomagnify (e.g., mercury, selenium) require the application of food chain multipliers (BAFs or BMF) to concentrations in prey organisms for higher trophic level predators. Concentrations of inorganic metals in a BAF or BCF study should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the substance is a micronutrient (e.g., selenium), while still below levels which adversely affect the species (EPA 1995b).[19] Bioaccumulation of inorganic metals may be inappropriately overestimated if concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms (EPA 1995b).

4.4.6.2 Polycyclic Aromatic Hydrocarbons (PAHsl

PAHs, also known as polynuclear aromatic hydrocarbons, or polynuclear aromatics, PNAs, are a class of compounds containing hydrogen and carbon in multiple ring structures. There are numerous possible PAH molecules, several of which are common analytes in a semivolatile compound analysis. PAHs are natural components of petroleum and are found in heavier petroleum fractions, such as lube oil, naphtha, etc. PAHs are also produced by the incomplete combustion of organic matter. For this reason, PAHs are ubiquitous in the environment at low levels, particularly in soil and sediments, to which they readily bind.

In general, PAHs are rapidly metabolized and considered unlikely to biomagnify despite their high lipid solubility (Eisler 1987). Inter- and in&a-species responses to individual PAHs are quite variable, however, and are significantly modified by many inorganic and organic compounds (Eisler 1987). Until these interactive effects are clarified, extrapolation of laboratory test results to field situations where there is suspected PAH contamination should proceed cautiously. The intermediate metabolites, however, have been identified as mutagenic, carcinogenic, and teratogenic agents (Sims and Overcash 1983). In most cases, the process of carcinogenesis occurs over a period of many months in experimental animals, although for some PAHs, malignancies may be induced by acute exposures to microgram quantities.

[19] Cam should be taken in using partitioning models to estimate BCFs or BAFs for soil-dependent organisms such as earthworms and plants. Models based on diffusivity constants and anaerobic conditions can result in unrealistically toxic concentrations (>1 percent) in the soil organism.

Amphibians are reported as quite resistant to PAH carcinogenesis when compared to mammals due to the amphibian's inability to produce mutagenic metabolities of BaP and perylene (Anderson, Doos, and Rose 1982). The ability to metabolize PAHs in nonmammalian species, however, is extremely variable and cannot be predicted on the basis of phylogenic associations. When PAHs are not metabolized, they have been shown to bioaccumulate and therefore pose a significant dietary route of exposure to predatory species. In species which can metabolize PAHs, one significant mode of toxicity is impairment of reproductive cycles.

Small mammals which burrow and ingest soil are likely to be the ecological receptors with the greatest potential exposure and risk from PAHs. Data are generally lacking on the acute and chronic toxicity of PAHs on avian wildlife (Eisler 1987). Eisler (1987) reports PAHs show little tendency for bioconcentration or biomagnification, particularly in terrestrial ecosystems, probably because most PAHs are rapidly metabolized. Beyer and Stafford (1993) also found PAH concentrations in earthworms to be well below soil levels. Gile, Collins, and Gillet (1982). however, report fairly high bioaccumulation factors for terrestrial species. In their 3-month mesocosm experiment using creosote coal tar distillate (which contained 21% phenanthrene and 9% acenaphthene), PAH concentrations in various animals were found to be elevated over average PAH soil concentrations.

PAHs can accumulate to some extent in terrestrial plants. Atmospheric deposition on leaves, however, is likely to be a more significant pathway than uptake from soil by roots (Vaughn 1984). Uptake of PAHs by plant roots is dependent on numerous factors including concentration, solubility, molecular weight of the PAH, and on the plant species (Edwards 1983).

4.4.6.3 Organochlorine Pesticides (OCPs) and Polychlorinated Biphenyls (PCBsl

OCPs and PCBs are extremely stable compounds and slow to degrade under environmental conditions. The toxicoiogical properties of individual PCBs and pesticides are influenced primarily by two factors: the partition coefficient, (K_{ow}), based on solubility in n-octanol/water, and stearic factors, resulting from different patterns of chlorine substitution. The more highly chlorinated forms of PCBs and pesticides tend to be more persistent, more strongly sorbed, less volatile, and less bioavailable (O'Connor, Chaney, and Ryan 1990, Sawhney 1988, Strek et al. 1981).

PCBs and pesticides are strongly sorbed in soils, sediments, and particulates in the environment, with levels usually highest in aquatic sediments containing microparticulates (Eisler 1986, EPA 1980, Duinker, Hillebrand, and Boon 1983). PCB and pesticide uptake from contaminated soils and sediments is governed by processes that include both direct incidental ingestion of contaminated soil/sediment particles and indirect ingestion via food webs or from parents to the fetus or embryo. Toxicity reports based on plant (terrestrial) uptake of pure PCBs and pesticides can be misleading because these chemicals are often added to the exposure medium at unreasonably high concentrations to facilitate analysis or they are added to coarse-textured soils extremely low in organic matter (O'Connor 1989).

PCBs, dioxins, and pesticides are all highly lipophilic, with the greatest concentrations occurring in fatty tissues. PCBs, dioxins, and pesticides are of greatest concern to higher trophic level predators. In mammals, these chemicals are readily absorbed through the gut, respiratory system, and skin, and can be transferred to young mammals either transplacentally or in breast milk. In birds, particularly endangered raptors, a reduction in eggshell thickness has been the endpoint of greatest concern from pesticides. Evidence implicating PCBs as a major source of eggshell thinning is inconclusive (Eisler 1986, Wiemeyer et al. 1984, Henny et al. 1984, Norheim and Kjos Hanssen 1984). Consideration of the potential bioaccumulative effects of PCBs, dioxins, and pesticides is important in the selection of appropriate assessment and measurement endpoints.

4.4.6.4 Chlorinated Dibenzo-p-dioxins and Dibenzofurans (CDDs/CDFs)

CDDs/CDFs, often abbreviated "dioxins and furans," are a group of chlorinated compounds based on the dibenzo-p-dioxin or dibenzofuran molecule (the two of which are structurally similar). CDDs/CDFs are not compounds used for commercial purposes in the past, and, outside of research, have no known use. Rather, CDDs/CDFs are byproducts of high temperature combustion of chlorinated compounds and impurities in other chemical products such as pentachlorophenol (CDDs) or polychlorinated biphenyls (CDFs). Although not considered a "natural" product, some forms of CDDs and CDFs (specifically octa-CDD and octa-CDF) are ubiquitous in the environment at very low concentrations.

There are 75 possible CDD congeners and 135 possible CDF congeners. As with PCBs, the degree of toxicity

varies with the degree and location of chlorination, becoming greatest when the 2, 3,7, and 8 positions of the molecule are substituted. The 2,3,7.8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) is considered the most potent CDD, and is the reference against which all other CDDs and CDFs are compared.

Analysis of CDDs and CDFs is most commonly reported by congener group (i.e., as either tri-, tetra-, penta-, hexa-, hepta, or octachlorodibenzop-dioxin or dibenzofuran). Within these groups, the results are often further separated into "2,3,7,8- substituted" or "other" categories. This form of reporting is needed to appropriately assess CDDs and CDFs. Reporting as "total dioxins" or even just by congener group may require the assumption that all CDDs/CDFs present are as toxic as 2,3,7,8-TCDD, resulting in an overestimate of potential risk posed by the presence of CDDs/CDFs.

Piscivorous fish and wildlife are thought to be particularly at risk from these chemicals due to their large exposure through aquatic food chains. The limited available toxicological data indicate that fish, especially salmonid sac fry, and mink *(Mustela vison)* are among the most sensitive animals to TCDD and related compounds. A recent assessment of the toxicity of these compounds along with environmental concentrations associated with TCDD risk to aquatic life and associated wildlife has been released by EPA (1993h).

Two basic methods are recommended for evaluating the toxicity of mixtures of PCBs, PCDFs, and PCDDS in environmental samples to determine sample "toxic equivalents" relative to TCDD (EPA 1993h). In the first method (commonly used in screening ERAs), individual PCB (Section 4.4.6.3), PCDF, and PCDD congeners are determined and multiplied by toxic equivalent factors (TEFs) to express potential toxicity in TCDD-equivalents (EQs). In the TEF approach for CDDs/CDFs, the toxicity of the TCDD compounds is expressed relative to the toxicity of 2,3,7,8-TCDD for mammalian systems (Safe 1990. Ankley et al. 1992). Soil or prey tissue doses of dioxins/furans may be calculated by applying congener-specific TEFs to the concentrations of the dioxins or furans prior to conversion of concentrations to doses. TEFs, however, are a species-specific construct and the TEF multipliers vary widely among species, depending on their ability to metabolize specific congeners. TEFs recommended by EPA (1995b) and Safe (1990) are frequently used in screening ERAs (see Exhibit 17). Recent publications (Newsted et al. 1995) presenting TEFs for fish should be considered for preferential use in aquatic risk assessments.

In the second method, the total PCB/PCDF/PCDD mixture is extracted from the environmental samples and then tested for potency, relative to TCDD, using a standard biological response (rat hepatoma cytochrome induction) as an endpoint (EPA 1993h). This latter approach bypasses the assumption of an additive model of toxicity for complex mixtures. If the latter biological approach for measuring TCDD-EQ is to be used for quantitative risk assessment, it is important to calibrate the biological system used with specific toxicological endpoints in the receptors of concern (EPA 1993h). Further discussion of TEFs for CDDs/CDFs can be found in *Interim Report on Data and Methods for Assessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin Risks to Aquatic Life and Associated Wildlife* (EPA 1993h). EPA's (1994g) dioxin wildlife workshop report, and in the GLWQI (EPA 1995b).

4.4.6.5 Total Petroleum Hydrocarbons (TPH) and Other Petroleum Groupings

TPH are common contaminants at DoD sites. Petroleum hydrocarbons originate from a variety of petroleum-derived fuels including jet fuel, fuel oils, and gasoline. Determination of the actual source material (gasoline versus fuel oil) is not always possible, particularly where site history is unknown. Composition of any given fuel will also vary depending on the source of the crude oil, refinery processes, and product specifications. Also, due to differential volatilization and biodegradation, the composition of the original fuel mixture in the environment is altered over time. Therefore, the toxicity of the insoluble and nonvolatile components remaining some time after a spill is often of more interest than volatile compound toxicity.

Because of the originally unknown and potentially altered composition of the spilled fuel, TPH toxicity is frequently assessed based on individually measured constituent toxicity, rather then by assessing the measured TPH concentration as a whole mixture. The primary constituents of petroleum components, such as paraffins and naphthenes, are generally not considered to be highly toxic (Amdur et al. 1991; Clayton and Clayton 1981) and are typically not included as COECs in ERAS. Aromatic constituents such as benzene and xylene and the carcinogenic PAH compounds are the primary COECs for risk assessments. Noncarcinogenic compounds, such as toluene, ethylbenzene, xylenes, naphthalene, and other noncarcinogenic PAH compounds, may be of concern for potentially acute toxic effects.

The impacts of TPH on terrestrial ecosystems are not as well documented as the impacts on aquatic ecosystems.*' Some attempts have been made in human health risk assessment to derive critical toxicity values for TPH. However, since the composition of TPH varies from place to place (even within the same site) as well as change in time (fresh versus aged product), it is unlikely that using critical toxicity values for this group of chemicals pro vi&s valuable descriptors of the potential toxicity of the components comprising the TPH detection. The BTEX and PAH compounds are currently used in characterizing potential risks and cleanup requirements for TPH because these chemical groups include the most toxic known TPH constituents and represent a broad range of physical and chemical properties influencing environmental mobility.

4.4.6.6 Military Chemicals

Many DoD sites contain potentially toxic chemicals not commonly found on nonmilitary sites. Military-specific chemicals may include explosives, rocket fuels, radioactive materials, chemical agents, or degradation products of these compounds. Because of the unique status of many military compounds, EPA is often unable to supply toxicity information. Profiles containing toxicological information relevant to an ERA can be obtained from USACHPPM and USAEC.[21] Technical reports that summarize environmental fate and behavior (plant uptake, mammalian and aquatic toxicology) of munitions material are also available in the open literature (Burrows et al. 1989, Cataldo, Harvey, and Fellows 1990, Layton et al. 1987). Pertinent information can also be obtained from site-specific environmental studies at installations such as Joliet AAP and Rocky Mountain Arsenal and by contacting the regional EPA or U.S. Army BTAG/ETAG **persons.** Appendix F presents several ecotoxicological profiles on military chemicals.

[20] The American Petroleum Institute (API) lists numerous reports regarding TPH toxicity in aquatic ecosystems. Effects concentrations in water for various oil products (bunker, crude, diesel, gasoline, jet fuel, lube oil), taxonomic group (invertebrates, fish, algae), and presence/absence of free product can be found in *A Critical Review of Toxicity Values and an Evaluation of the Persistence of Petroleum Products for Use in Natural Resource Damage Assessments,* API, April 5, 1993.

[21] Contacts for toxicity information on military chemicals: USAEC (Mr. Robert Muhly @ 410-612-6839 and Ms. Mary Ellen Maly @ 410-671-1523); USACHPPM (Dr. Glen Leach @ 410-671-3980).

4.4.6.7 Toxicologic Uncertaintles

Use of EPA-derived aquatic and wildlife toxicity values should be examined with regard to the degree of uncertainty associated with their development. The uncertainties associated with the values should be stated in the effects characterization, and the impact of applying the value estimated, specifically (when the assessment is complete) for chemicals that are major contributors to overall site risks and hazards. The following factors should be addressed:

- What are the cumulative uncertainties and modifying factors applied to derive the RTV?
- Is the form of the chemical used in derivation of the toxicity value the same or similar to that in the environmental medium being assessed?
- Is the duration of the toxicological benchmark study relevant to the exposure conditions for the key receptors being assessed? Actual exposure durations for key receptors may or may not exceed the test duration periods on which the RTVs are based.
- Was the medium applicable to the toxicological study used to derive the toxicity value (e.g., the chemical was administered to the test animal in food, water) similar to the medium being assessed? Could matrix effects or water effects be important in bioavailability?
- Has any route-to-route extrapolation been performed? Was it reasonable to do so, and were assumptions used in the extrapolation appropriate?
- Were surrogate toxicity values (toxicity values for other chemicals that are structurally and/or chemically similar) used for chemicals that do not possess values? Was this approach reasonnable?
- Were BCFs or BAFs applied in the development of the RTV? BAFs and BCFs developed for one study may be quite different than bioaccumulation factors at other areas.

The potential exists for wildlife species to be more or less sensitive than laboratory test species and the derived toxicological benchmarks. Toxicity benchmark values for laboratory organisms may be substantially lower than

those for wildlife due to the sensitive strains of laboratory animals used, the direct means by which they are dosed, and the need to obtain a satisfactory toxic response. The LD_{50} studies are usually designed to promote maximum exposure (absorption) because less of the chemical complexes with dietary material. The LD_{10} dietary studies probably give a better indication of the toxicity of the chemical tested, while NOEL levels from longer studies are the best (still imperfect) laboratory studies to be used as predictors of field effects. On the other hand, laboratory species may be less sensitive than their wild counterparts in that they must be hardy enough to be amenable to culturing in a laboratory setting or endure animal husbandry and handling.

In contrast to laboratory tests of terrestrial organisms, laboratory tests of aquatic invertebrates or fish show that the tested chemicals may be less toxic to the same or similar animals under natural conditions. This is because the tested chemical is not as bioavailable in natural waters due to the modifying effect of other water quality characteristics (e.g., pH, hardness, suspended solids). In order to estimate the toxicity of a chemical under natural conditions (a Tier II or higher effort), a parallel series of toxicity tests are run using site water and laboratory test water as dilution water and then calculating a WER (site water LC_{50}/lab water LC_{50}).

4.5 Risk Characterization

Risk characterization includes two major steps: risk estimation and risk description (EPA 1992a). The risk estimation consists of comparing the exposure and toxicity profiles, as well as estimating and summarizing the associated uncertainties and assumptions to characterize current and potential adverse biological effects posed by the COECs. The potential impacts from all exposure routes (direct contact, ingestion, and inhalation) and all media (water, sediment, soil, and air) are included in this evaluation as appropriate according to EPA guidance (EPA 1989c). The risk description consists of a summary of the results of the risk estimation and uncertainty analysis and an assessment of confidence in the risk estimates through a discussion of the weight of evidence. The risk description can also include a discussion of additional data or analyses that might reduce the uncertainty in the risk estimates. These additional data collection efforts or analyses would be conducted in subsequent tiers.

4.51 Risk Estimation

In Tier I, risk estimation can be either qualitative or quantitative, depending on the data available, DQOs, and the stated level of effort. Typically, the Tier I risk estimation is performed through a series of quantitative quotient calculations that compare exposure values with RTVs. The RTVs, as derived from literature benchmark values, serve in this case as surrogate measurement endpoints. Simple ratios of exposure values to RTVs are known as HQs which are summed (where appropriate) for all chemicals and exposure pathways for a given receptor to pro vide the HI. The HI method is described below. Quantitative risk estimation techniques can be fairly simple or more complex, depending on the complexity of the food webs and exposure pathways that are to be quantified. Other quantitative approaches that are used in the higher tiers include comparing probabilistic distributions of effects, and exposure and simulation modeling.

Characterization of adverse effects on key receptor species at the population, community, or ecosystem level is generally more qualitative in nature than characterizing human risks. This is because the toxicological effects of most chemicals am not well documented for most species. RTVs that are usable and applicable for the evaluation of ecological effects in ecosystems are generally limited. In the estimation and characterization of risk, the adverse effects of chemicals on populations and habitats should be considered rather than the effects on individual members of a species according to EPA guidance (1989c, 1989a), except in the case of threatened and endangered species, where individuals require protection in order to preserve the population. True risk estimation, therefore, also involves interpretation of results, with professional judgment, to provide the ecological implication of the observations, made at the level of the measurement endpoint. In some cases, this may involve a great deal of professional judgment. In others, the ecological implications are either obvious or inherent due to the level of the chosen measurement endpoint.

4.51.1 Objectives

Most ERAs and nearly all Tier I ERAs provide a comparison of single effect values (RTVs) with predicted or measured exposure concentrations for one or more key receptors. In risk estimation, the chemical intakes

calculated in the exposure characterization are combined with the appropriate critical toxicity values identified in the effects characterization. The results are the estimated ecological hazards posed by the exposures. This ratio or quotient of the exposure value to the effects value (i.e., RTV) provides the risk calculation. Along with the numerical calculations (quotients) of potential ecological risks (hazards), a narrative describing the primary contributors to ecological risks and factors qualifying the results is presented.

4.5.1.2 Ecological Evaluation Techniques

A variety of ecological evaluation tools, techniques, or approaches may be used to evaluate and estimate the magnitude and importance of the risk. Such techniques vary in level of effort, sophistication, and cost, but the most sophisticated or time-consuming techniques are not necessarily the most appropriate to a given site. Many of these evaluation techniques are more appropriately conducted as part of a Tier II, III, or IV effort (see Sections 5.0 through 7.0). Assessment of chemical effects on key receptors is directly dependent on the use of evaluation techniques appropriate for the assessment and measurement endpoints. Decisions as to which techniques to use should be well-documented and follow HTRW *Technical Project Planning Guidance* (USACE 1995b).

Each of the evaluation techniques has its own unique advantages and disadvantages in terms of the data and information provided. Some of these tools are useful to measure effects at the individual operable unit and species level: e.g., field sampling of tissue residues. Tools, such as Habitat Evaluation Procedures (HEP) (USFWS 1987) and Index of Biological Integrity (IBI) (Karr et al. 1986) can be used to quantify injury to biological resources at the community/ecosystem level by measuring reductions in habitat quality. Others such as toxicity tests are used to characterize cumulative hazards from multiple chemicals with no attempt to apportion chemical contribution from the individual OUs or to discern mechanisms of chemical interactions. Tools such as probabilistic pathways analysis are most appropriate when there is an endangered species at risk from chemicals that bioaccumulate. To measure critical ecosystem functions such as nutrient cycling, tools other than those listed may be needed.

Each technique has its own peculiarities in terms of the interpretation of results, and many of these tools cannot account for such phenomena as biological resistance. Also, some of these tools are restricted as far as their applicability (e.g., Wetland Evaluation Technique [WET] and the sediment-water equilibrium partitioning approach may only be used in wetlands). No single species test, indicator parameter analysis, statistical procedure, or field inspection review can address the complex nature and extent of contamination or risk in biological systems. Impacts at one hierarchal level do not always translate easily into effects at other levels, and emergent system-level properties cannot be studied at lower levels of organization (Kimball and Levin 1985). Chains of influence are common features of ecosystems, and indirect effects, which can be more important than direct effects, often predominate in ecosystems (Kimball and Levin 1985, Johnson et al. 1991). To thoroughly evaluate ecosystem risk, multimedia (i.e., air, water, soil, sediment, and biota) as well as different trophic and hierarchal (organism, community, population, ecosystem) levels may all need to be addressed or measured.

Examples of some ecological valuation techniques and tools (and references where descriptions of the approach may be found) include:

- HQs and HIs.
- Sediment-Water Equilibrium Partitioning (EP) or Water Quality Approach (Long and Morgan 1990).
- Evaluation of Dredged Material Proposed for Ocean Dumping (EPA 1991g).
- Screening Level Concentration Approach (Long and Morgan 1990).
- Apparent Effects Threshold (AET) or Species Approach (Long and Morgan 1990).
- Bioeffect/Contaminant Co-Occurrence Analyses (COA) Approach (Long and Morgan 1990).
- Sediment Quality Triad Approach (Chapman 1989).
- Rapid Bioassessment Protocols for Use in Streams and Rivers (EPA 1989j).
- Sediment Quality Criteria Approach (Chapman 1989).
- Bioassay Approach (Toxicity Tests) (EPA 1989c).
- Diversity Indices (Pielou 1975).

- Species Richness/Relative Abundance Indices.
- WET (USACE 1987).
- IBI (Karr et al. 1986).
- HEP (USFWS 1987).
- Exposure Pathway Analysis (Fordham and Reagan 1991).
- Probabilistic/Sensitivity/Uncertainty Analysis (Macintosh. Suter, and Hoffman 1994).
- Linear Structural Modeling (Johnson, Huggins, and DeNoyelles 1991).
- Linked Deterministic and Simulation Models.

4.5.1.3 Terrestrial Ecosystem Methodologies

The following sections present descriptions of two methodologies for performing quantitative risk characterization for terrestrial and aquatic ecosystems. Methodologies for characterizing risk to receptors in terrestrial and aquatic ecosystems are similar in some aspects, but are discussed separately **because** of differences in the data forming **the** basis for the final risk calculations.

4.5.13.1 Hazard Quotient (HQ) Method. The HQ method as applied to ecological risk is similar **to that** for calculating an HQ for human health risk characterization. The objective of a risk characterization for a specific receptor is to compare the estimated chemical intake of one chemical through one exposure route with the "threshold" concentration, that is, the level of intake that is recognized as unlikely to result in adverse ecological effects (i.e., the reference toxicity value, RTV). The comparison (quotient) of estimated intake and acceptable exposure level is called an HQ and is derived in the following manner:

$$HQ = \frac{\text{intake (mg/kg-bw/day)}}{\text{RVT (mg/kg-bw/day)}}$$

where the intake is the chronic or subchronic daily intake (expressed as a dose in mg/kg-bw/d) of the chemical (whichever is appropriate for the exposure being assessed) and the RTV is the corresponding threshold value (subchronic or chronic, oral) expressed as a dose. Short-term, subchronic, and chronic exposures should be assessed separately.

The HQ is used as a basis for deciding whether or not there is a negligible potential for ecological impacts. An HQ of 1 indicates that the estimated intake is the same as the RTV; an HQ of greater than 1 indicates the estimated intake is greater (i.e., the threshold has been exceeded): less than 1, it is less (i.e., the threshold has not been exceeded). The interpretation of the results of an HQ is outlined by Barnthouse et al. (1986) and others. In general, an HQ greater than 1 is interpreted as a level at which adverse ecological effects may occur. An HQ less than 1 does not indicate a lack of risk, but should be interpreted based on the severity of the reported effect and the magnitude of the HQ.

The HQ should not be viewed as a statistical value or risk: for example, an HQ of 0.01 does not indicate a l-in-100 probability of the adverse effect occurring. Rather, it indicates that the intake is 100 times less than the RTV for the chemical. In addition, the Intake/RTV ratio does not infer a linear relationship, i.e., the hazards posed by exposure to the chemical do not increase linearly as the HQ increases linearly. This is so for several reasons, including the fact that RTVs are not precise descriptors of hazard (developed by using multiple uncertainty factors), and the severity of potential ecological effects varies with different chemicals (dose-response relationships differ).

To examine the potential for the occurrence of adverse ecological effects as a result of exposure to multiple chemicals through multiple exposure pathways, it is assumed that an adverse effect could occur if the sum of the HQs exceeds 1. In other words, even if exposure to each individual chemical is below its RTV (HQ ratio less than 1). if the sum of the ratios for multiple chemicals exceed unity, adverse ecological effects could occur. This is quantitatively derived in the following manner

$$HQ_i + HQ_i + HQ_i \ldots . + HQ_i = HI_j$$

where HQ_i is the HQ for an individual chemical and HI_j is the HI for a specific exposure pathway. To derive an overall HI, considering multiple co-occurring exposure pathways (and multiple chemicals), the following is performed:

$$HI_j + HI_j + HI_j \ldots . + HI_j = \text{Overall HI}$$

HIs should be expressed to one significant figure only, because of the uncertainties involved in deriving the RTVs. In addition, HIs should be reported in decimal form (e.g., 0.001, not 0.0012 or $1x10^{-3}$).

Deriving an overall I-II using an additive approach assumes the following:

- All chemicals will result in a similar adverse effect by the same mechanism of action (or same target organ).

- Each chemical exerts its effect independently (i.e., there is no synergism or antagonism).

Applying the assumption of additivity is a conservative approach that likely overestimates the actual potential ecological risk presented by the exposure. However, if the overall HI is greater than unity, consideration should be given to the known types of adverse ecological effects posed by exposure to the chemicals. If the assumption of additivity is not valid (i.e., if the chemicals most strongly contributing to the exceedance of the HI display very different types of adverse effects), the HI may be segregated according to toxicological endpoint. These segregated HIs may then be examined independently.

Segregation of HIs according to toxicological endpoints requires an expert understanding of toxicology and should be performed only by qualified individuals. Factors that need to be considered include the critical toxicological effect upon which the RTV is based, as well as other toxicological effects posed by the chemical at doses higher than the critical effect. Major categories of toxic effects include neurotoxicity, developmental toxicity, immunotoxicity, reproductive toxicity, and individual target organ effects (hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, dermal, and ocular) (EPA 1989f).

4.5.1.3.2 Probabilistic Methodologies. Probabilistic methodologies, which use distributions of effects levels and exposure estimates (as opposed to single exposure point estimates), may be used in the development of risk estimates. Risk is quantified by the degree of overlap between the two distributions -- the more the overlap, the greater the risk. To apply probabilistic methods such as these and to construct valid distributions, it is important that sufficient data amenable to statistical treatment are available[22] Collection of **such data, if not** available, may be more appropriately performed as a Tier II or higher effort. where actual field data are available.

Probabilistic methods can also be used for developing more appropriate exposure concentrations, where factors such as area use need to be considered. For mobile receptors such as fish, large herbivores, and predators, determination of dietary exposure concentrations should be "area" (i.e., feeding range) based rather than "point" (i.e., fixed location) based. Using probabilistic uncertainty analyses methods to create models that simulate random walks, probable exposure conditions for mobile receptors can be estimated under different time scenarios (daily, weekly, monthly, yearly).

A probabilistic uncertainty analysis, such as the Monte Carlo simulation, examines the range of potential exposures associated with the distribution of values for select or all input parameters of the risk algorithm. Probability density functions are assigned to each parameter, then values from these distributions are randomly selected and inserted into the exposure equation. After this process is completed many times, a distribution of predicted values is generated that reflects the overall uncertainty of inputs to the calculation. The results are presented graphically as the cumulative exposure probability distribution curve. In this curve, the exposure associated with the 50th percentile of the exposure may be viewed as the "average" exposure and those exposures associated with the 90th or 99.9th percentile may be viewed as "high end" exposure.

[22] Although relatively simple to execute, probabilistic methodologies should be applied judiciously in ERAs (Burmaster and Anderson 1994). Using a probabilistic distribution for intake values and RTVs is only as appropriate as the quality of the input data. For example, using probabilistic distributions to account for a wide range of literature benchmark values that have not been reviewed for quality or applicability to site-specific conditions and receptors would not be appropriate.

Several computer-based proprietary simulation programs are available with which to conduct this simulation. Performance of a Monte Carlo simulation should only be performed by professionals with an understanding of the assumptions and limitations of using it, including such factors as identifying the appropriate number of runs and correlated input variables. An example of a Monte Carlo simulation is presented in Appendix E.

4.5.1.4 Aquatic Ecosystem Methods

The HQ and probabilistic quantitative methods can also be used for the estimation of risk to aquatic ecological receptors. The primary difference between aquatic and terrestrial receptors is that contaminant concentrations in surface water or sediments are used as input to the calculations instead of body-weight-based dose concentrations.

For calculation of an aquatic HQ, the comparison of a measured concentration in water or sediment with an appropriate aquatic RTV is as follows:

$$HQ = \frac{\text{measured concentration(mg/l)}}{\text{aquaticRTV(mg/l)}}$$

where the measured concentration may be the overall RME concentration, maximum concentration, or other appropriate measurement of exposure concentration and the aquatic RTV is the AWQC, sediment criteria (units would be mg/kg), or a species-specific RTV. As in the description of HQs for terrestrial receptors, an HQ greater than 1 is generally interpreted as a level at which adverse ecological effects may occur. An HQ less than 1 does not indicate lack of risk, but should be interpreted based on the severity of the potential reported effect and the magnitude of the calculated quotient.

HIs for multiple chemicals and multiple exposure pathways are the sums of individual HQs and pathway-specific HIs, respectively. It is only appropriate to sum the HQs for contaminants with the same toxic effect mechanisms (e.g., PAHs).

Probabilistic methods can also be used to estimate aquatic risk. Instead of using exposure concentrations in soils or forage, however, probability distributions of chemical concentrations in surface water or sediments are used. Comparisons of measured chemical concentrations can be made to probability distributions or point estimates of aquatic RTVs.

A number of other potential quantitative methods are available for use with aquatic receptors. In fact, nearly all of the ecological evaluation techniques previously listed are applicable to aquatic receptors.

4.5.2 Characterization of Uncertainty

In a Tier I ERA, uncertainty is usually presented as a qualitative discussion about the range of confidence in the risk estimation (i.e., low, medium, or high) accompanied by the factors that may contribute to an overestimation or underestimation of risk. Wherever possible, risk should be expressed in terms of magnitude, direction (over- or underestimation), and probability, using either a sensitivity analysis (examining the appropriateness of the risk estimation by maximizing one or more values) or a probabilistic analysis. By expressing risk in quantitative terms of probability, plus magnitude and direction, the risk manager is better enabled to make judgments on risks relative to other factors (such as costs), and not simply decide that uncertainty levels in the risk assessment must be reduced by further study.

452.1 Objectives

EPA has identified two requirements for full characterization of risk. First, the characterization must address qualitative and quantitative features of the assessment through a weight-of-evidence discussion. This was discussed in the preceding section. Second, it must identify any important uncertainties in the assessment. This section discusses methods of identifying and describing uncertainties in a risk assessment.

Full disclosure and clear articulation of risk uncertainties are guiding principles for this portion of the risk assessment (EPA 1992g, 1995a,d).

> "EPA risk assessors and managers need to be completely candid about confidence and uncertainties in describing risks and in explaining regulatory decisions. Specifically, the Agency's risk assessment guidelines call for full and open discussion of uncertainties in the body of each EPA risk assessment, including prominent display of critical uncertainties in the risk characterization. Numerical risk estimates should always be accompanied by descriptive information carefully selected to ensure an objective and balanced characterization of risk in risk assessment reports and regulatory documents." (EPA 1992g).

Identification and discussion of uncertainty in an assessment is important for several reasons (EPA 1992g):

- Information from different sources carries different kinds of uncertainty, and knowledge of these differences is important when uncertainties are combined for characterizing risk.
- Decisions must be made on expending resources to acquire additional information to reduce uncertainties.
- A clear and explicit statement of the implications and limitations of a risk assessment requires a clear and explicit statement of related uncertainties.
- Uncertainty analysis gives the decision-maker a better understanding of the implications and limitations of the assessments.

The output from the uncertainty analysis is an evaluation of the impact of the uncertainties on the overall assessment and, when feasible, a description of the ways in which uncertainty could be reduced (EPA 1992a).

4.5.2.2 Sources of Uncertainty in a Risk Assessment

Sources of uncertainty in a risk assessment exist in almost every component of the assessment. Uncertainty generally can arise from two main sources: variability and data gaps. Model error is an additional, potential main source of uncertainty that a risk assessor may encounter. Uncertainty from variability can enter a risk assessment through random or systematic error in measurements and inherent variability in the extent of exposure of receptors. Uncertainty from data gaps is most prominently seen in the screening or Tier I ERA, when numerous approximations are made regarding exposures, chemical fate and transport, intakes, and toxicity.

In the following sections, specific sources of uncertainty in a risk assessment are identified and discussed. Following this discussion, different approaches to conducting an uncertainty evaluation are presented.

The identification of the types and numbers of environmental samples, sampling procedures, and sample analysis all contain components that contribute to uncertainties in the risk assessment. Decisions regarding the scope of sampling and analysis are often made based on the ECSM developed at the planning stages of the investigation. While appropriate planning may minimize the uncertainty associated with these components, some uncertainty will always exist, because the "real" state of the site is unknown prior to sampling and, in fact, may not be fully elucidated even after sampling.

Some of the assumptions in this component that contribute to uncertainty in the assessment include:

- Media Sampled. Unless a decision has been made to sample all media, often a subset of media is selected for sampling and analysis. This selection is usually based upon the anticipated presence of a chemical in a medium from the site history and the chemical's chemical and physical properties and may not include consideration of potential transport through biological media. If all abiotic media in which a chemical is actually present have not been sampled, appropriate risks may not be described.
- Locations Sam&d. The type of sampling strategy selected may impact the uncertainty associated with the results. For example, purposive sampling (sampling at locations assumed to contain the chemicals) will likely result in a higher frequency of chemical detection and concentration than random sampling or systemized grid sampling. Therefore, use of the results may skew the assessment toward greater assumed exposures.
- Number of Samples. Fewer samples result in a higher degree of uncertainty in the results. This is demonstrated in the summary statistics, specifically the 95% UCL, in which the statistical descriptor ("t" or "II" value), and hence the 95% UCL, increases with a smaller number of samples. Planning for and success in obtaining a specific number of samples to reach a specific degree of statistical confidence can limit the degree of uncertainty.
- Sampling Process. The sampling process itself can contribute to uncertainties in the data from a number of factors, including sampling contamination (cross-contamination from other sample locations, introduction of chemicals used in the field); poorly conducted field procedures (poor filtering, incomplete cornpositing); inappropriate sample storage (head-space left in containers of volatile sample containers, inappropriate storage temperatures); sample loss or breakage: and

other factors. Some of these factors can be controlled by an adequate SAP; however, planning does not prevent the occurrence of sampling errors.

- Analytical Methodology. The analytical methodology can contribute to uncertainty in a number of ways, including the scope of the chemicals analyzed (if analysis of all important chemicals was not performed): the detection or quantitation limits applied (if not sufficient): and limitations in the analysis due to matrix effects, chemical interferences, poorly conducted analyses, or instrumentation problems. Some of these factors can be addressed in up-front planning (such as selection of the analytical method); others cannot (e.g., instrumentation problems).

- Stochasticity. Natural variability is a basic characteristic of ecological systems, as well as the factors which influence such systems (e.g., weather). Of all the contributions to uncertainty, stochasticity is the only one that can be acknowledged and described but not reduced (Suter in EPA 1992a).

Evaluation of the data to select COECs for the ERA may result in uncertainties. Application of selection criteria may inadvertently result in the inappropriate exclusion or inclusion of chemicals as COECs. Improper inclusion or exclusion of chemicals can result in an underestimation (if inappropriately removed) or overestimation (if inappropriately retained) of potential ecological risks. Uncertainties associated with the selection criteria include the following:

- Background Comparison. If background measurements are not truly representative of background conditions, chemicals may be inappropriately retained or removed from the list of COECs.

- Sample Contamination. Uncertainty in the assessment can occur if chemicals are not recognized as being present as a result of sampling or laboratory introduction and are included as COECs.

- Frequency of Detection. Use of a high detection frequency (say, over 5%) as a selection criterion may result in the inappropriate exclusion of chemicals as COECs.

- Toxicity/Concentration Screening. Removal of chemicals as COECs as a result of using a toxicity/concentration screen can result in uncertainty in the assessment, since some chemical contributors to the risk (even if not significant) have been removed

It is possible that the wildlife selected as key receptors in an ERA am not those receptors that have the greatest likelihood of being at risk or are sensitive to a particular chemical. Reptiles and amphibians are typically not addressed in ERAS, as exposure and toxicity data on which to base an assessment are generally lacking. Ecosystem and community level assessment endpoints such as adverse impacts to nutrient cycling, predator-prey relationships, community metabolism, and structural shifts are typically not addressed in ERAs. Uncertainty is associated with the professional judgment used in the selection of key receptors.

The ECSM is the product of the problem formulation phase, which in turn, provides the foundation for the effects characterization and risk estimation. If incorrect assumptions are made during development of the ECSM regarding the potential toxic effects or the ecosystems and receptors potentially impacted, then the final risk characterization may be seriously flawed.

Numerous assumptions regarding the amount of chemical intake by a receptor are commonly made as part of the exposure characterization. Such exposure estimates are associated with a number of uncertainties that relate to the inherent variability of the values for a given parameter (such as body weight) and to uncertainty concerning the representativeness of the assumptions and methods used. Uncertainties associated with chemical intake and exposure include:

- Potential Exposure Pathways. Potential exposure pathways are identified by examining the current and future land uses of the site and the fate and transport potential of the COECs. While current land use and potential exposure pathways are often easy to identify, potential future uses can only be inferred from information available at the current time. For many ERAs, potential future land use is assumed to be the same as current land use. This and any assumption regarding future land use, any potential future migration of contaminants offsite, and exposure pathways will add uncertainty to the assessment.

- Potentially Exposed Receptors. As discussed in the preceding bullet, identification of potentially exposed receptors is based upon information currently available. Assumed exposed receptors under future use scenarios can only be guessed at, and this adds uncertainty to the assessment.

- Exposure and Intake Factors. Point values (e.g., maximum or 95% UCL) for exposure estimates are commonly used in risk assessments rather than a distribution of exposure values that describe the distribution of exposures. These point values are usually conservative, and their use results in introduction of conservatism into the risk assessment that should be addressed. Use of average (i.e., central tendency), rather than upper-end exposure and intake factors may underestimate potential health risks, since only half the population is exposed to that degree or less; the other half is exposed to a greater degree. Using average values, therefore, also contributes to uncertainty that should be addressed in the assessment.

  Food and soil/sediment intake values for most wildlife are either unknown or highly variable and very site-specific. Food and sediment intake values for key receptors may be derived from allometric equations. Determining chemical concentrations in food may require the use of bioconcentration or bioaccumulation factors. Uncertainty exists in the use of such equations and factors.

- Exposure Point Concentrations. Exposure point concentrations may be derived either from measured site media chemical concentrations alone or in combination with fate and transport modeling. With regard to estimating exposure point concentrations from sampling data alone, use of 95% UCL and mean concentrations is associated with some degree of uncertainty. The 95% UCL concentration is used to limit the uncertainty of estimating the true mean concentration from the sample mean concentration. This value may overestimate the true mean concentration. Use of the sample mean concentration may under- or overestimate the true mean concentration.

  Application of fate and transport modeling adds an additional tier of potential uncertainty to exposure point estimates. Models cannot predict "true" exposure point concentrations at different times and places or in different media, but provide an estimate of the potential concentration under certain assumptions. Often, the assumptions used in the models are conservative to avoid underestimating potential concentrations. In addition, not all applicable processes are or can be considered (e.g., degradation, removal processes).

RTVs are developed from literature benchmark values by applying conservative assumptions, and are intended to protect sensitive species or populations. Use of non-site-specific, generic RTVs will usually result in overestimates of potential risk. Factors that contribute to uncertainty include:

- Use of UFs in the RTV. RTVs are primarily derived from laboratory animal toxicity studies performed at high doses to which UFs of 10 or more are applied.

- **Choice of Literature Benchmark Study to Derive an RTV. The inclusion or exclusion of studies in the derivation of an RTV is usually made by professional judgment; this affects the numerical RTV value.**

- The Assumption of the Most Sensitive Species. When deriving RTVs, the animal study showing an adverse effect at the lowest exposure or intake level is often the basis for deriving the RTV. EPA assumes that wildlife receptors are at least as sensitive as the most sensitive laboratory animal used (toxicological data on wildlife are still very limited). The LD_{10} dietary studies probably give a better indication of the toxicity of the chemical tested than LD_{50} studies, while NOAELs from longer studies are the best (still imperfect) laboratory studies to use as predictors of field effects. The potential exists for wildlife species to be more or less sensitive than test species (some biota can adapt) and the toxicological benchmarks used Various uncertainty factors may be used to account for differences in taxonomic levels (i.e., species, genus, order, family) between the test species for the RTV and the key receptor(s) under consideration.

- Exposure Duration. Actual exposure durations for key receptors may or may not exceed the test duration periods on which the toxic literature benchmark value and resultant RTV are based. Because mobile receptors are likely to feed or

visit several locations, or avoid contaminated areas, their daily dose, if averaged over time, could be less than that used for evaluating risk. Unless exposure modifying factors are used, risk is likely to be overestimated.

Standardized algorithms to calculate chemical intakes and associated risks ate generally lacking for many wildlife receptors. There are numerous assumptions inherent in use of such equations that add uncertainty to the assessment. These include:

- Assumption of Additivity. Calculation of HIs assumes (at least as a first line approach) additivity of toxic effects. This assumption adds uncertainty to the assessment, and may result in an overestimate or underestimate of potential risks, depending on whether synergistic or antagonistic conditions apply.

- Omission of Certain Factors. Exposure modifying factors, such as absorption, bioavailability, soil matrix effects, area use, and exposure frequency should be considered. In cases where these processes are important, use of a standard algorithm without modification may result in an overestimation of potential chemical intakes.

4.5.2.3 Evaluation of Uncertainty

Various approaches can be applied to describe the uncertainties of the assessment, tanging from descriptive to quantitative. The method selected should be consistent with the level of complexity of the assessment. It may be appropriate to conduct an indepth quantitative evaluation of uncertainty for a detailed, complex assessment, but may not be appropriate or even needed for a screening level or simplistic assessment. In the section below, qualitative and quantitative approaches to expressing uncertainty are discussed.

4.5.2.3.1 Qualitative Evaluation. A qualitative evaluation of uncertainty is a descriptive discussion of the sources of uncertainty in an assessment, an estimation of the degree of uncertainty associated with each source (low, medium, high), and an estimate of the direction of uncertainty contributed by that source (under- or overestimation). A qualitative uncertainty assessment does not provide alternate risk values, but provides a framework in which to place the risk estimates generated in the assessment.

4.5.2.3.2 Quantitative Evaluation. A quantitative uncertainty assessment is any type of assessment in which the uncertainty is examined quantitatively, and can take several forms. A sensitivity analysis is one form in which specific parameters are modified individually and resultant alternate risk estimates are derived. Probabilistic approaches, which were described previously, are more complex forms of uncertainty analyses that simultaneously examine the combined uncertainty contributed by a number of parameters. An example of this approach, *Analysis of Extrapolation Error,* is presented in Barnthouse et al. (1986).

A sensitivity analysis is the process of changing one variable while leaving the others constant and determining the effect on the output. These results am used to identify the variables that have the greatest effect on exposure. This analysis is performed in three steps:

- Define the numerical range over which each parameter varies.

- Examine the relative impact each parameter value has on the risk and hazard estimates.

- Calculate the approximate ratio of maximum and minimum exposures obtained when range limits for a given parameter are applied to the risk algorithm. Exposure parameters should not, however, be combined in ways that are not reasonable: for example, combining maximum intake rates with minimum body weight.

4.5.3 Risk Description

Risk description has two primary elements. The first is the ecological risk summary, which summarizes the results of the risk estimation and uncertainty analysis and assesses confidence in the risk estimate through a discussion of the weight of evidence (EPA 1992a). The second element is interpretation of ecological significance, which describes the magnitude of the identified risks to the assessment endpoint and the accompanying uncertainty (EPA 1992a). A third element, discussion of the effect of additional data or analyses on uncertainty, should also be included.

4.5.3.1 Ecological Risk Summary

The ecological risk summary presents the results and uncertainties of the quantitative risk analysis. Weight-of-evidence discussions should be provided in the risk summary. The identification of data gaps and the need to conduct or not conduct additional analyses through another iteration (tier level) of the risk assessment process should be identified at this step.

4.5.3.1.1 Summary of Risk Estimation and Uncertainty. Every ERA should present the actual intake and risk calculations performed for the site in an appendix to the report. These calculations should show the chemical concentrations, the intake/exposure values, and the RTVs (including derivation) for each chemical assessed. A summary table should also be presented in the body of the risk assessment that provides a synopsis of the results of the quantitative assessment. This summary table should include the following factors:

- Receptor name
- All exposure pathways assessed for the receptor
- Risk and/or HI for each pathway
  - Expressed to one significant figure only
  - Short-term, subchronic, and chronic, as appropriate
  - Average and high end exposure
- Predominant chemical, i.e., the chemical contributing the greatest amount to the risk or hazard estimate
- Overall HI

A discussion should accompany the presentation of the quantitative risk estimates that interprets and qualifies the results, and highlights the important factors inherent in the values. Conclusions of the risk estimation should be described as some type of quantitative statement (e.g., there is a 20 percent chance of 50 percent mortality) (EPA 1992a). The uncertainties identified during the risk assessment are summarized either quantitatively or qualitatively, and the relative contribution of the various uncertainties to the risk estimates should be discussed wherever possible.

The summary of ecological risk should relate back to the originally selected assessment endpoints. The scale of the assessment endpoint is an important consideration in the overall interpretation of risk. Some degree of mortality, for example, can occur in a population without resultant significant adverse effects on the population.[23]

45.3.1.2 Weight of Evidence. In the characterization of ecological risk, the information collected concerning the identified hazards, the receptors, and the exposure characterization are integrated through a comprehensive ecotoxicological evaluation of source-receptor exposure pathways. After identifying sensitive receptors and habitats, complete exposure pathways, exposure points, and COEC exposure point concentrations, the potential for impacts is evaluated either quantitatively, qualitatively, or a combination of the two. Results from a variety of measurement techniques, such as toxicity tests and HIs, may be used in the weight-of-evidence characterization of potential and actual ecological risk.

If actual or potential adverse impacts are found, those impacts am further evaluated to determine to what extent they are site-related and to determine appropriate remediation goals. The ERA also includes conclusions regarding impacts from site chemicals, and a qualitative evaluation of limitations and uncertainties associated with those conclusions.

4.5.3.2 Interpretation of Ecological Significance

The interpretation of risk provides a critical link between the estimation of risks and the communication of assessment results. Ranges or levels that are considered acceptable by EPA are presented and discussed in the following sections.

4.5.3.2.1 Factors Influencing Ecological Significance. The relative significance of different effects may require further interpretation, especially when changes in several assessment or measurement endpoints are observed or

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[23] Although highly controversial, a 20% population reduction level is proposed by some as an acceptable threshold (Hull and Suter 1993). Selection of an appropriate and acceptable population reduction level ultimately depends on the site-specific population parameters and assessment endpoint for the receptor(s) of concern.

predicted (EPA 1992a). If the ERA is concerned with adverse impacts on a variety of receptors and different ecosystems, qualitative discussions should be presented as to the nature and magnitude of the potential adverse effects associated with each receptor and ecosystem.

The spatial and temporal distributions of the effect provide another perspective important to interpreting ecological significance (EPA 1992a). Adverse effects to a resource that is small in scale relative to the site and/or area of contamination (e.g., a wetland or nesting grounds) may have a small spatial effect, but may represent a significant degradation of the resource because of its overall scarcity. Recovery potential is another factor influencing ecological significance that may need to be considered depending on the assessment endpoints (EPA 1992a).

4.5.3.2.2 Interpreting Site-Wide Ecological Significance. It is often the case at large Federal facilities that individual chemicals and ecological receptors are not isolated in the environment, and adverse effects are not necessarily related to a limited number of chemicals confined to the immediate location of discharge. Organizing the ERA to interpret the ecological significance of various chemicals to which a variety of ecological receptors are exposed at sometimes distant locations is challenging.

One means to organize and systematically consider the ecological significance of multiple receptors and multiple exposure pathways at large, complex sites is through the use of simplified ranking matrices (Figures 4-1 and 4-2) for important ecological receptors, based on the likelihood that they may be impacted by a specified pathway or numerous exposure pathways and COECs or COEC groups. For example, in the matrix shown in Figure 4-1, individual species (e.g., eagle or hawk) or groups of organisms with similar feeding strategies and habitat preferences (e.g., seed-eating birds, fish) arc listed in the left column. Across the top of the matrix are the chemical groups (e.g., heavy metals, pesticides and PCBs, munitions), exposure media (surface soils and surface water), and ingestion routes (primary or secondary). Differences in exposure between primary and secondary ingestion are principally due to differences in relative tendencies of the listed chemical groups to bioaccumulate and biomagnify through the food web. Each potentially completed exposure pathway is indicated by either an open (possible exposure) or a filled-in circle (potentially significant exposures).

This initial qualitative screening is done on a site-wide basis in order to refine the list of receptors that would be evaluated at smaller, separate locations (e.g., SWMUs or OUs). Completion of the matrix presented in Figure 4-2 provides identification of those key receptors likely to be at greatest risk, as well as those pathways which likely pose the greatest risk to various receptors at the facility. By identifying receptor(s) potentially at greatest risk and exposure pathways which potentially pose the greatest risk, the risk assessment process becomes more focused and manageable for interpretation. This same matrix (Figure 4-2) can also be used to rank COECs for each identified key receptor/exposure pathway combination.

Matrix ranking processes may be subjective, as in this example, or quantitative (depending on data availability) based on site characterization, ecotoxicological information, and EPA guidance. The ranking process may incorporate weighting factors to emphasize specific factors (e.g., area use, toxicity, exposure area, bioavailability, and biomagnification potential) which affect the ability of the chemicals considered to have a deleterious impact on the ecological receptors. Matrices can be updated or revised during the risk assessment process should additional data regarding the COECs, exposure pathways, or key receptors be identified. The additional data will enhance risk decisions for smaller locations within the facility (e.g., OUs/SWMUs) for which the risk assessment process has not been completed.

4.5.3.2.3 Discussion of Additional Data or Analyses. The third element, the risk description, serves as a conclusion and is an evaluation of the level of uncertainty and the potential for reducing the uncertainty by conducting additional analyses of the existing data, or collecting additional data and analyzing these data. The types of data needed to reduce the uncertainty (i.e., the data gaps) are examined, and an assessment of which tier to enter is made. Detailed descriptions of Tiers II, III, and IV are provided in Sections 5.0 through 7.0.

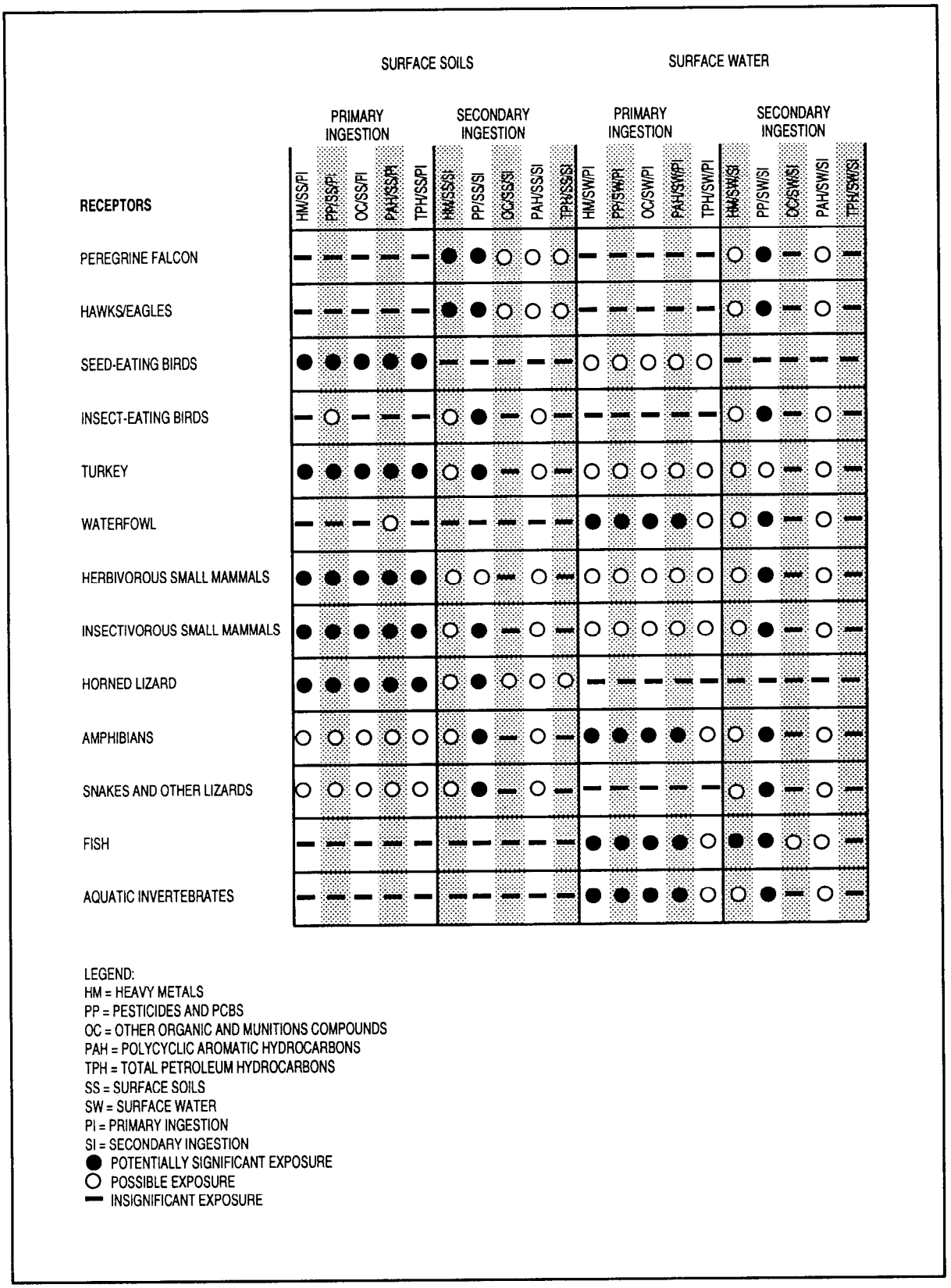

Figure 4-1. Site-wide exposure matrix

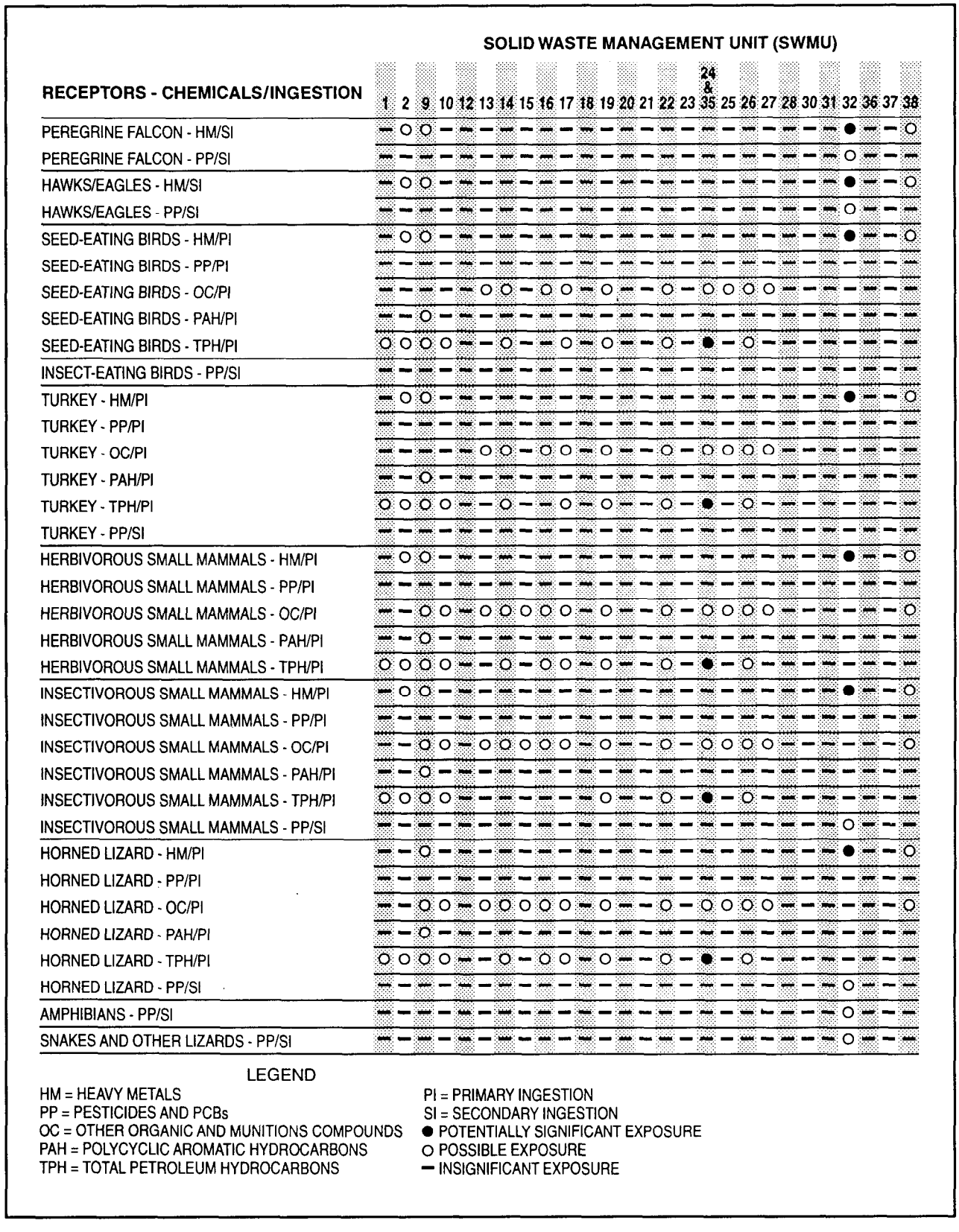

Figure 4-2. SWMU specific exposure matrix